5/8/2023

4:42 PM

Received by
EPA Region VIII
Hearing Clerk

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

IN THE MATTER OF: **Berkey International LLC** Royal Industrial Park, B-2 869 Km 1.5, Barrio Palmas Catano, Puerto Rico 00962 PO Box 2206, Orocovis, Puerto Rico 00720 Respondent.	Docket No. FIFRA-08-2023-0038 FIFRA SECTION 13(a) STOP SALE, USE, or REMOVAL ORDER

I. AUTHORITY

1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.

2. The undersigned EPA official has been duly authorized to issue this Order.

II. GOVERNING LAW

3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a.

4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.

5. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."

6. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)."

7. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator established that "an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is: . . . [a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs … and cosmetics . . . ." 40 C.F.R. § 152.5(d).

8. Section 2(h) of FIFRA, 7 U.S.C. § 136(u), defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer…."

9. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."

10. The regulation at 40 C.F.R. § 152.3 further defines the term "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any state."

11. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers" and defines "labeling" in part, as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide."

12. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, a pesticide is misbranded if:

> (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular;
>
> (B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
>
> (C) it is an imitation of, or is offered under the name of, another pesticide;
>
> (D) its label does not bear the registration number assigned under section 136e of this title [FIFRA section 7] to each establishment in which it was produced;
>
> (E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], are adequate to protect health and the environment; [or]

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], is adequate to protect health and the environment[.]

13. Section 2(q)(2) of FIFRA, 7 U.S.C. § 136(q)(2), provides that, among other reasons, a pesticide is misbranded if:

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot clearly be read, a label bearing—
(i) the name and address of the producer, registrant, or other person for whom produced;
(ii) the name, brand, or trademark under which the pesticide is sold;
(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and
(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification[.]

14. FIFRA's labeling requirements at 40 C.F.R. part 156 require that labels for pesticide products must contain several pieces of information, including the producing establishment number, hazard and precautionary statement, and directions for use. 40 C.F.R. § 156.10(a).

III. BASIS FOR THE ORDER

15. Respondent, Berkey International LLC, is a limited liability company organized under the laws of Puerto Rico and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), subject to FIFRA and its implementing regulations.

16. On November 22, 2022, a representative of the EPA inspected the facility of James Enterprise Inc. doing business as Berkey Filters (JEI), located at 1976 Aspen Circle, Pueblo, Colorado 81006, to determine compliance with FIFRA.

17. At that November 2022 inspection, the EPA observed **Black Berkey Filters** and products containing **Black Berkey Filters** being held for distribution and sale.

a.

18. The **Black Berkey Filter** product is a water filtration unit that is used in multiple products and may be purchased as part of those products or on its own.

19. **Travel Berkey Water Filters**, **Big Berkey Water Filters**, **Royal Berkey Water Filters**, **Imperial Berkey Water Filters** and **Crown Berkey Water Filters (Black Berkey Filter Products**) are sold with **Black Berkey Filters** inserted in the apparatus.

20. At the November 2022 inspection, EPA Inspectors observed that the **Black Berkey Filter** labeling included the following language:

> "Black Berkey Purification Elements:
> VIRUSES: >99.999%
> PATHOGENIC BACTERIA (AND SURROGATES)
> >99.9999% -Exceeds Purification Standard (Log 6): Bacillius atrophaeus (Anthrax Surrogate)".

21. At the time of the November 2022 inspection, the EPA observed the following statements regarding **Black Berkey Filter Products** on the website, https://www.berkeyfilters.com/products/black-berkey-filter:

a. "Composition[:] Black Berkey Filters are made of a carbon composite containing high-grade coconut shell carbon combined with a proprietary blend of 5 other types of media."
b. "Our Black Berkey® Filters (sometimes called Black Berkey Elements) are world famous for good reasons. Read below to learn how the Black Berkey® Filters used in all of our systems make purified water. It's a more encompassing level of H20 filtration!"
c. "The Black Berkey Filters used in all of our systems take water filtration to a whole new level! During testing conducted by independent, EPA-approved laboratories, the Black Berkey Filters removed a long list of water contaminants with never-before-seen results and significantly raised the standard for the water filter industry."
d. "A pair of Black Berkey Filters comes standard in all of Berkey Water Filter Systems, including the Big Berkey."
e. "When drinking water that's been filtered using a Black Berkey Filter, you can rest assured that your water is clean and safe for consumption. In fact, Black Berkey purification elements are far more powerful compared to competitors' water filters."
f. "We tested the filters with more than 10,000 times the concentration of harmful pathogens per liter of water than is required by industry-standard test protocols. This concentration of pathogens is so high that the water exiting the filters should be expected to contain a concentration of 100,000 or more pathogens per liter (99.99% reduction — the requirement in order to be classified for pathogenic removal)."
g. "Incredibly, Black Berkey water filter elements removed 100% of the pathogens."
h. "After using the Black Berkey Filters, absolutely no pathogens were found in the effluent or were able to be detected. This set a new standard, allowing us to classify all systems containing the Black Berkey Filters as purifiers."

22. At the time of the November 2022 inspection, the EPA observed the following statements regarding **Black Berkey Filter Products** on the website, https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html:

> "Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water."

23. These claims indicate that **Black Berkey Filter Products** are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, pesticides pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).

24. None of the **Black Berkey Filter Products** are registered with the EPA.

25. None of the **Black Berkey Filter Product** labels bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced, making them misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).

26. As a result of that November 2022 inspection, the EPA issued a Stop Sale, Use, or Removal Order, FIFRA-08-2023-0011, pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), and ordered JEI to immediately cease the sale, use, or removal of all **Berkey Black Filter Products**, **Sport Berkey Replacement Filters**, and **Sport Berkey Water Bottle** units under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of the Stop Sale, Use, or Removal Order, FIFRA-08-2023-0011.

27. As part of the investigation related to the Stop Sale, Use, or Removal Order, FIFRA-08-2023-0011, the EPA received information related to the products referenced in the FIFRA Stop Sale, Use, or Removal Order, FIFRA-08-2023-0011.

28. EPA has information demonstrating the following:

    a. Respondent sold or distributed **Big Berkey Water Filters**;
    b. Respondent sold or distributed **Travel Berkey Water Filters**;
    c. Respondent sold or distributed **Crown Berkey Water Filters**;
    d. Respondent sold or distributed **Imperial Berkey Water Filters**;
    e. Respondent sold or distributed **Royal Berkey Water Filters**; and
    f. Respondent sold or distributed **Travel Berkey Water Filters**:

29. Accordingly, EPA has reason to believe that Respondent sold or distributed the following **Berkey Black Filter Products**: **Travel Berkey Water Filters**, **Big Berkey Water Filters**, **Royal Berkey Water Filters**, **Imperial Berkey Water Filters**, and **Crown Berkey Water Filters.**

30. EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell, the unregistered pesticides, **Black Berkey Filter Products** in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

31. EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell, the misbranded pesticides **Black Berkey Filter Products** in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

IV. ORDER

32. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all **Black Berkey Filter Products,** under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.

33. The **Black Berkey Filter Products** shall not be sold, offered for sale, held for sale, shipped, delivered for shipment, received; or, having been so received, delivered, offered for delivery, moved, or removed, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.

34. Should Respondent seek an exception to this Order's prohibitions, Respondent may submit a request to EPA, in accordance with the following:

    a) Requests must be made in writing by electronic mail to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, at tokarz.christine@epa.gov.

    b) Any request for movement or removal must include a written accounting of the products to be moved, including the quantity (type, number, and volume of containers) to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and an explanation of the reasons for the request.

    c) If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA, including proof of compliance with all applicable federal, state, and local laws.

    d) Any movement or removal of any **Black Berkey Filter Products** made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the distribution or sale of an unregistered and misbranded pesticide in violation of FIFRA.

35. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of the **Black Berkey Filter Products** subject to this Order. The accounting must be submitted to Christine Tokarz, at the e-mail address above, and must include the following:

    a) The complete list of media used in the composition of **Black Berkey Filters.**

    b) An accounting of all existing product inventory at any of Respondent's facilities or warehouses, including the location(s) where the products are held, quantities, and container sizes;

    c) A list of each shipment of the **Black Berkey Filter Products** en route to any of Respondent's establishments from any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amount held by each type of container, the name and address or

addresses from which the shipment was shipped and the destination establishment(s); and

d) A list of each shipment of **Black Berkey Filter Products** en route from any of Respondent's establishments to any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amounts held by each type of container, the establishment from which the shipment was shipped and the destination establishment(s).

36. Respondent must provide EPA with an updated accounting at least every 30 days thereafter until Respondent no longer has any **Black Berkey Filter Products** in its ownership, custody or control.

37. The information requested herein must be provided whether Respondent regards part or all of it as a trade secret or confidential business information. Respondent is entitled to assert a claim of business confidentiality in accordance with the regulations at 40 C.F.R. § 2.203(b) by labeling such information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a properly made claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. If Respondent does not make a proper claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Respondent.

V. OTHER MATTERS

38. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.

39. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.

40. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.

41. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.

42. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.

43. If any provision of this Order is subsequently held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY REGION 8

Date: _____ By: DAVID COBB Digitally signed by DAVID COBB Date: 2023.05.04 18:07:03 -06'00'

David Cobb, Section Supervisor
Toxics and Pesticides Enforcement Section
Enforcement and Compliance Assurance Division

12/27/2022

7:00am

Received by
EPA Region VIII
Hearing Clerk

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

IN THE MATTER OF: **James Enterprise, Inc.** **DBA Berkey Filters** 1976 Aspen Circle Pueblo, Colorado 81006 Respondent.	)	Docket No. FIFRA-08-2023-0011 FIFRA SECTION 13(a) STOP SALE, USE, or REMOVAL ORDER

I. AUTHORITY

1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. § 136k(a), which authorizes the Administrator of EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.

2. The undersigned EPA official has been duly authorized to issue this Order.

II. GOVERNING LAW

3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a.

4. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.

5. Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), provides that it shall be unlawful for any person who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by FIFRA.

6. Section 12(a)(2)(S) of FIFRA, 7 U.S.C. § 136j(a)(2)(S), provides that it shall be unlawful for any person to violate any regulation issued under sections 3(a) or 19 of FIFRA.

7. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."

8. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism (except viruses, bacteria, or other microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)."

9. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator established that "an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is: . . . [a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs … and cosmetics . . . ." 40 C.F.R. § 152.5(d).

10. Section 2(h) of FIFRA, 7 U.S.C. § 136(u), defines "pesticide" as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer…."

11. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "to distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."

12. The regulation at 40 C.F.R. § 152.3 further defines the term "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any state."

13. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers" and defines "labeling" in part, as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide."

14. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, a pesticide is misbranded if:

> (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular;
>
> (B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
>
> (C) it is an imitation of, or is offered under the name of, another pesticide;
>
> (D) its label does not bear the registration number assigned under section 136e of this title [FIFRA section 7] to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], are adequate to protect health and the environment; [or]

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title [FIFRA section 3(d)], is adequate to protect health and the environment[.]

15. Section 2(q)(2) of FIFRA, 7 U.S.C. § 136(q)(2), provides that, among other reasons, a pesticide is misbranded if:

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot clearly be read, a label bearing—
(i) the name and address of the producer, registrant, or other person for whom produced;
(ii) the name, brand, or trademark under which the pesticide is sold;
(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and
(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification[.]

16. FIFRA's labeling requirements at 40 C.F.R. part 156 require that labels for pesticide products must contain several pieces of information, including the producing establishment number, hazard and precautionary statement, and directions for use. 40 C.F.R. § 156.10(a).

III. BASIS FOR THE ORDER

17. Respondent James Enterprise, Inc., doing business as Berkey Filters, is a corporation organized under the laws of the State of Colorado and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), subject to FIFRA and its implementing regulations.

18. On November 22, 2022, a representative of the EPA inspected Respondent's facility located at 1976 Aspen Circle, Pueblo, Colorado 81006 (the Facility), to determine Respondent's compliance with FIFRA (the Inspection).

19. Upon review of the information collected at the Inspection and upon review of Respondent's website, www.berkeyfilters.com, the EPA has reason to believe Respondent distributed or sold, and continues to distribute or sell unregistered and misbranded pesticides, specifically **Black Berkey**

Filters, **Sport Berkey Replacement Filters**, **Travel Berkey Water Filters**, **Big Berkey Water Filters**, **Royal Berkey Water Filters**, **Imperial Berkey Water Filters**, **Crown Berkey Water Filters, Berkey Light Water Filters**, and **Sport Berkey Water Bottles**, in violation of FIFRA.

A. Black Berkey Filters and Products Sold with Black Berkey Filters (Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, and Berkey Light Water Filters)

20. The **Black Berkey Filter** product is a water filtration unit that is used in multiple products and may be purchased as part of those products or on its own.

21. **Travel Berkey Water Filters**, **Big Berkey Water Filters**, **Royal Berkey Water Filters**, **Imperial Berkey Water Filters**, **Crown Berkey Water Filters** and **Berkey Light Water Filters** are sold with **Berkey Black Filters** inserted in the apparatus and will be referenced as "**Berkey Black Filter Products**".

22. **Black Berkey Filter** labeling includes the following language:
"Black Berkey Purification Elements:
VIRUSES: >99.999%
PATHOGENIC BACTERIA (AND SURROGATES)
>99.9999% -Exceeds Purification Standard (Log 6): Bacillius atrophaeus (Anthrax Surrogate)".

23. The EPA observed that Respondent had **Berkey Black Filter Products** at its Facility being held for distribution or sale, and that it offers them for sale and distribution online through its website, https://www.berkeyfilters.com/products/black-berkey-filter.

24. **Berkey Black Filter Products** are available for purchase online at: https://www.berkeyfilters.com/products/black-berkey-filter.

25. The EPA observed the following statements regarding **Berkey Black Filter Products** on the site, https://www.berkeyfilters.com/products/black-berkey-filter:

a. "Composition[:] Black Berkey Filters are made of a carbon composite containing high-grade coconut shell carbon combined with a proprietary blend of 5 other types of media."
b. "Our Black Berkey® Filters (sometimes called Black Berkey Elements) are world famous for good reasons. Read below to learn how the Black Berkey® Filters used in all of our systems make purified water. It's a more encompassing level of H20 filtration!"
c. "The Black Berkey Filters used in all of our systems take water filtration to a whole new level! During testing conducted by independent, EPA-approved laboratories, the Black Berkey Filters removed a long list of water contaminants with never-before-seen results and significantly raised the standard for the water filter industry."
d. "A pair of Black Berkey Filters comes standard in all of Berkey Water Filter Systems, including the Big Berkey."

e. "When drinking water that's been filtered using a Black Berkey Filter, you can rest assured that your water is clean and safe for consumption. In fact, Black Berkey purification elements are far more powerful compared to competitors' water filters."
f. "We tested the filters with more than 10,000 times the concentration of harmful pathogens per liter of water than is required by industry-standard test protocols. This concentration of pathogens is so high that the water exiting the filters should be expected to contain a concentration of 100,000 or more pathogens per liter (99.99% reduction — the requirement in order to be classified for pathogenic removal)."
g. "Incredibly, Black Berkey water filter elements removed 100% of the pathogens."
h. "After using the Black Berkey Filters, absolutely no pathogens were found in the effluent or were able to be detected. This set a new standard, allowing us to classify all systems containing the Black Berkey Filters as purifiers."

26. The EPA observed the following statements regarding **Berkey Black Filter Products** on the site, https://berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html:

> "Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements. Testing was conducted both internally and by Analytical Services, Inc. to ensure that the silver used does not leach into the purified water."

27. These claims indicate that **Berkey Black Filter Products** are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, pesticides pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).

28. None of the **Berkey Black Filter Products** are registered with the EPA.

29. None of the **Berkey Black Filter Product** labels bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced, making them misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).

30. Respondent distributed or sold, and continues to distribute or sell, the unregistered pesticides, **Berkey Black Filter Products** in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

31. Respondent distributed or sold, and continues to distribute or sell, the misbranded pesticides **Berkey Black Filter Products** in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

B. Sport Berkey Replacement Filter and Products Sold with Sport Berkey Replacement Filter (Sport Berkey Water Bottles)

32. The **Sport Berkey Replacement Filter** product is a water filtration unit that is used in the **Sport Berkey Water Bottles** and may be purchased as part of that product or on its own.

33. **Sport Berkey Replacement Filter** products are available to purchase online at https://www.berkeyfilters.com/products/berkey-sport-filter.

34. A brochure for the Sport Berkey Filter available at https://cdn.shopify.com/s/files/1/0167/5480/2788/files/The_Sport_Berkey.pdf?11355, states:

> "The media within the filter element removes contaminants by a surface phenomenon known as 'adsorption' which results from the molecular attraction of substances to the surface of the media. As the bottle is pressed, the source water is forced through the filter. The quality and volume of media used, determine the rate of adsorption. The flow rate or time of exposure through the filter has been calculated to yield the greatest volume removal of toxic chemicals caused by pollution from industry and agriculture. This exclusive filter also incorporates proprietary absorbing media that are impregnated into the micro-porous filter for the IONIC absorption of pollutants into the filter such as aluminum, cadmium, chromium, copper, lead, mercury, and other dangerous heavy metals."

35. The **Sport Berkey Replacement Filter** website: https://www.berkeyfilters.com/products/berkey-sport-filter, includes the following claims:

> a. "This is the factory original replacement for the filter in the Sport Berkey Water Bottle and has the same filtration medium as the larger Black Berkey Filter element."
> b. "The Sport Berkey® Portable Water Filter is the ideal personal protection traveling companion — featuring the IONIC ADSORPTION MICRO FILTRATION SYSTEM. The theory behind this innovation is simple. The bottle's filter is designed to remove and/or dramatically reduce a vast array of health-threatening contaminants from questionable sources of water, including remote lakes and streams, stagnant ponds and water supplies in foreign countries where regulations may be sub standard, at best."
> c. "The Sport Berkey® Portable Water Filter eliminates or reduces: Harmful microscopic pathogens."

36. The EPA observed that Respondent had **Sport Berkey Replacement Filter** products at its Facility being held for distribution or sale, and that it offers the product for sale and distribution online through its website https://www.berkeyfilters.com/products/berkey-sport-filter.

37. These claims on the **Sport Berkey Replacement Filter** product's labeling indicate that **Sport Berkey Replacement Filter** is a substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus a pesticide pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).

38. The **Sport Berkey Replacement Filter** label does not contain an EPA Registration Number or any other information regarding registration of the **Sport Berkey Replacement Filter** as a pesticide with the EPA.

39. The EPA has not registered the **Sport Berkey Replacement Filter**.

40. The **Sport Berkey Replacement Filter** label does not bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced.

41. Because of the lack of an EPA establishment registration number on the label, **Sport Berkey Replacement Filter** is misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).

42. The **Sport Berkey Water Bottles** are sold with the **Sport Berkey Replacement Filters** inserted in the apparatus.

43. Because the **Sport Berkey Water Bottles** are sold with the **Sport Berkey Replacement Filters** inserted in the apparatus, and because the pesticidal claims associated with the **Sport Berkey Replacement Filters** accompany the **Sport Berkey Water Bottles**, the **Sport Berkey Water Bottles** is also a pesticide pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).

44. The EPA has not registered the **Sport Berkey Water Bottle**.

45. The **Sport Berkey Water Bottle** label does not bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced.

46. Because of the lack of an EPA establishment registration number on the label, **Sport Berkey Water Bottle** is misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).

47. Respondent distributed or sold, and continues to distribute or sell, the following unregistered pesticides, the **Sport Berkey Replacement Filters** and the **Sport Berkey Water Bottle**, in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

48. The Respondent distributed or sold, and continues to distribute or sell, the following misbranded pesticides, the **Sport Berkey Replacement Filters** and the **Sport Berkey Water Bottles**, in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

IV. ORDER

49. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all **Berkey Black Filter Products, Sport Berkey Replacement Filters**, and **Sport Berkey Water Bottle** units ("**Subject Products**") under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.

50. The **Subject Products** shall not be sold, offered for sale, held for sale, shipped, delivered for shipment, received; or, having been so received, delivered, offered for delivery, moved, or removed, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.

51. Should Respondent seek an exception to this Order's prohibitions, Respondent may submit a request to EPA, in accordance with the following:

a) Requests must be made in writing by electronic mail to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, at tokarz.christine@epa.gov.

b) Any request for movement or removal must include a written accounting of the products to be moved, including the quantity (type, number, and volume of containers) to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and an explanation of the reasons for the request.

c) If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA, including proof of compliance with all applicable federal, state, and local laws.

d) Any movement or removal of any **Subject Products** made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the distribution or sale of an unregistered and misbranded pesticide in violation of FIFRA.

52. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of the **Subject Products** subject to this Order. The accounting must be submitted to Christine Tokarz, at the e-mail address above, and must include the following:

a) The complete list of media used in the composition of **Black Berkey Filters** and **Sport Berkey Replacement Filters.**

b) An accounting of all existing product inventory at any of Respondent's facilities or warehouses, including the location(s) where the products are held, quantities, and container sizes;

c) A list of each shipment of the **Subject Products** en route to any of Respondent's establishments from any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amount held by each type of container, the name and address or addresses from which the shipment was shipped and the destination establishment(s); and

d) A list of each shipment of **Subject Products** en route from any of Respondent's establishments to any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amounts held by each type of container, the establishment from which the shipment was shipped and the destination establishment(s).

53. Respondent must provide EPA with an updated accounting at least every 30 days thereafter until Respondent no longer has any **Subject Products** in its ownership, custody or control.

54. The information requested herein must be provided whether Respondent regards part or all of it as a trade secret or confidential business information. Respondent is entitled to assert a claim of business confidentiality in accordance with the regulations at 40 C.F.R. § 2.203(b) by labeling such

information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a properly made claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. If Respondent does not make a proper claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Respondent.

V. OTHER MATTERS

55. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.

56. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.

57. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.

58. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.

59. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.

60. If any provision of this Order is subsequently held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY REGION 8

Date: _____ By: DAVID COBB Digitally signed by DAVID COBB Date: 2022.12.22 11:26:00 -07'00'

David Cobb, Section Supervisor
Toxics and Pesticides Enforcement Section
Enforcement and Compliance Assurance Division

HEINONLINE

Citation: 41 Fed. Reg. 51065 1976



Content downloaded/printed from
HeinOnline (http://heinonline.org)
Wed Jun 24 15:54:41 2015

-- Your use of this HeinOnline PDF indicates your acceptance
of HeinOnline's Terms and Conditions of the license
agreement available at http://heinonline.org/HOL/License

-- The search text of this PDF is generated from
uncorrected OCR text.

EPA Reg. No. 6735-201. Tide Products, Inc., Box 1020, Edinburg TX 78533. TIDE MALATHION 5 DUST. Active Ingredients: Malathion (0,0-dimethyl dithiophosphate of diethyl mercaptosuccinate) 5%. Method of Support: Application proceeds under 2(b) of interim policy. Application for reregistration. PM16

EPA File Symbol 6962-LR. Madison Bionics, 11250 W. Addision St., Franklin Park, IL 60131. PROPER. Active Ingredients: Ammonium Oxalate 1.30%; 2,2'-Methylenebis (3,4,6-Trichlorophenol) 0.30%; Ammonium Ethylene Diamine Tetraacetate 0.20%; 2,4,4' - Trichloro-2' - hydroxydiphenylether 0.10%; Ammonium Ortho Phenylphenate 0.05%. Method of Support: Application proceeds under 2(b) of interim policy. PM32

EPA File Symbol 6962-LE. Madison Bionics. DISINFECTANT 4045. Active Ingredients: Isopropanol 15.00%; Potassium orthophenylphenate 4.40%; Potassium o-benzyl-p-chlorophenate 4.05%; Tetrasodium ethylenediamine tetraacetate 1.60%. Method of Support: Application proceeds under 2(a) of interim policy. PM32

EPA File Symbol 8075-A. Allen Chemical Co., 3235 N. W. 37th St., Miami FL 33142. ALCO TOWER BIOCIDE #13. Active Ingredients: Disodium cyanodithiomidocarbonate 3.68%; Potassium N-methyldithiocarbamate 5.07%. Method of Support: Application proceeds under 2(b) of interim policy. PM33

[FR Doc.76-34122 Filed 11-18-76;8:45 am]

[FRL 646-5]

PEST CONTRAL DEVICES AND DEVICE PRODUCERS

Consolidation and Clarification of Requirements

I. Purpose

• Requirements applicable to pest control devices and device producers have been set forth in various regulations promulgated pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136 et seq.) ("FIFRA" or "the Act"). The purpose of this notice is to provide a consolidation and clarification of all such requirements. •

II. Definitions

At section 2(h) of FIFRA (7 U.S.C. 136(h)) the term "device" is defined to mean:

* * * any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separtely therefrom.

To more clearly identify the types of products to which the requirements discussed in this Notice apply, the term "device" must be contrasted with the term "pesticide," which is defined at section 2(u) of FIFRA to mean:

* * * any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as plant regulator, defoliant, or desiccant.

Thus, if an article uses physical or mechanical means to trap, destroy, repeal, or mitigate any plant or animal life declared to be a pest at 40 CFR 162.14, it is considered to be a device. If the article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide.

III. Devices Subject to the Act

Section 25(c)(4) of FIFRA (7 U.S.C. 136w(c)(4)) provides that the Administrator may specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) (7 U.S.C. 136(q)(1)) or section 7 (7 U.S.C. 136e) of this Act upon his determination that application of such provision is necessary to effectuate the purposes of this Act. On July 3, 1975, the Administrator promulgated regulations (40 F.R. 28242) amending 40 CFR Part 162 pursuant to this authority. 40 CFR 162.15 now provides that devices as defined in FIFRA section 2(h) are subject to the requirements of FIFRA section 2(q)(1)(A)-(G) and to those provisions of FIFRA section 7 which are necessary to effectuate the purposes of FIFRA with respect to devices.

The preamble to these regulations at 40 F.R. 28266 declared that to effectuate the purposes of the Act, devices subject to sections 2(q)(1) and 7 include but are not limited to:

(A) Certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances or mixtures of substances which are pesticides), and ultrasonic devices, for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites; (B) certain high frequency sound generators, carbide cannons, foils, and rotating devices, for which claims are made to repel birds; (C) black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper, for which claims are made to kill or entrap certain insects; and (D) mole thumpers, sound repellents, foils and rotating devices, for which claims are made to repel certain mammals.

The preamble further specifies those instruments declared to be of a character unnecessary to be subject to this Act in order to carry out the purposes of the Act. These include:

(1) Those which depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself, and

(2) Those which operate to entrap vertebrate animals.

Products generally falling within these two categories include rat and mouse traps, fly swatters, tillage equipment for weed control and fish traps.

Section 8 of FIFRA (7 U.S.C. 136f) provides for such record-keeping and record inspection requirements as the Administrator determines necessary for effective enforcement of the Act. Section 17 specifies the requirements to be placed on the import and export of devices. In neither of these sections is there a provision that the Administrator declare those classes of devices subject to these sections of the Act; and in the attendant regulations, no specification is made. For purposes of enforcement, the Agency will consider those classes of devices declared to be subject to regulation under section 25(c)(4) of the Act as subject to regulation under sections 8 and 17 as well.

IV. Summary of FIFRA Provisions Applicable to Devices

Any instrument declared to be a device under 40 CFR 162.15 is, upon introduction into channels of trade, subject to the provisions discussed below. Those provisions of the amended FIFRA which pertain to devices are in many respects similar to those under the 1947 FIFRA (61 Stat. 163; 7 U.S.C. 135-135k). In both Acts the Agency is authorized to inspect records showing the delivery, movement, or holding of devices (7 U.S.C. 135c, 136f); to obtain samples of any device in the marketplace (7 U.S.C. 135d, 136g); to seize any misbranded device (7 U.S.C. 135g, 136k); to initiate criminal proceedings against any person violating any provision of the Act (7 U.S.C. 135f, 136l); and, in cooperation with the Secretary of the Treasury, to sample, examine, and detain any imported device which violates the provisions of the Act (7 U.S.C. 135h, 136o).

The differences in the provisions of the two Acts with respect to requirements applicable to devices, lie primarily in the greater specification of jurisdiction and regulatory requirements provided by the 1972 amendments. For example, while a device, unlike a pesticide, is not subject to the section 3 registration requirement of FIFRA, section 12 of the Act makes clear the intent of the Act that subject devices and persons dealing with devices be held responsible for those obligations, other than registration, that are imposed by the Act. Jurisdiction to regulate devices is expanded to intra- as well as interstate commerce (7 U.S.C. 136j(a)(1)). Similarly, section 9(a) of the amended FIFRA specifies that entry for the purpose of inspecting and obtaining samples of devices "packaged, labeled, and released for shipment is permitted into "any establishment or other place where * * * devices are held for distribution or sale (7 U.S.C. 136g(a)).

With respect to affirmative regulatory requirements, section 2(q)(1) of the amended FIFRA expands the definition of misbranding as it applies to devices subject to the Act (7 U.S.C. 136(q)(1)). Section 7 of the amended FIFRA is totally new, requiring the registration of establishments which produce devices declared subject to the Act (7 U.S.C. 136e). In addition to the provisions of the Act allowing the inspection of records kept by producers and distributors of devices, section 8(a) of the amended FIFRA requires producers of devices subject to the Act to maintain such books and records as the Administrator requires by regulation (7 U.S.C. 136f(a)). Finally, section 17(a) of FIFRA, as amended, specifically imposes the same recordkeeping requirements on producers of devices intended for export by making such producers subject to the requirements of section 8.

AR0000020

V. ELABORATION OF SPECIFIC REQUIREMENTS APPLICABLE TO DEVICES

A. *Section 2(q)(1), Misbranding Provisions (7 U.S.C. 136(q)(1)).* With promulgation of the regulations at 40 CFR 162.15, which invoked the authority of section 25(c)(4) to specify devices subject to sections 2(q) and 7 of the Act, the labeling requirements of the 1947 FIFRA to which devices had been subject were expanded (7 U.S.C. 135(z)(1)). Those misbranding provisions of section 2(q)(1) of the amended FIFRA which the Administrator has made applicable to devices are listed at 40 CFR Part 162.15(b). In summary, a device will be subject to enforcement action if

2(q)(1)(A): Its labeling bears any statements, designs, or graphic representations relative thereto or to its ingredients which are false or misleading in any particular;
2(q)(1)(B): Its packaging or wrapping fails to conform with standards established pursuant to section 25(c)(3) (Such standards have not, as of this date, been issued by the Administrator; at such time as they are, the question of their applicability to devices will be addressed);
2(q)(1)(C): It is an imitation of, or is offered for sale under the name of another device;
2(q)(1)(D): Its label fails to bear the establishment number;
2(q)(1)(E): Required information is not prominently displayed on the label;
2(q)(1)(F): It lacks adequate directions for use; or
2(q)(1)(G): It lacks an adequate warning or caution statement.

40 CFR 162.10(a)(5) provides an interpretation of what the term "false and misleading" may include in the context of FIFRA section 2(q)(1)(A) misbranding:

A false or misleading statement concerning the composition of the product;
A false or misleading statement concerning the effectiveness of the product;
A false or misleading statement about the value of the product for purposes other than as a device;
A falle or misleading comparison with other devices;
Any statement directly or indirectly implying that the device is recommended or endorsed by any agency of the Federal Government;
A true statement used in such a way as to give a false or misleading impression to the purchaser;
Label disclaimers which negate or detract from labeling statements required under the Act and regulations; or
Non-numerical and/or comparative statements on the safety of the product.

B. Section 7, Registration of Establishments (7 U.S.C. 136e). On November 6, 1973, regulations (40 CFR Part 167) for the implementation of section 7, Registration of Establishments, were published in the FEDERAL REGISTER (38 F.R. 30557). The scope of the requirements is set forth at § 167.2(a): "All establishments, as defined in this part, which produce any pesticide or device subject to the provisions of this section, must be registered pursuant to the requirements of these regulations * * *" At § 167.1(k) the term "device" is defined as "* * * any device or class of devices as defined by the Act and determined by the Administrator pursuant to section 25(c) to be subject to the provisions of section 7 of the Act."

Section 7 imposes three basic requirements: (1) Registration of device-producing establishments, (2) labeling which reflects the EPA establishment number assigned to the establishment in which the device was produced, and (3) submission of annual production reports.

All establishments in which devices subject to the Act are produced must be registered with the Environmental Protection Agency as producing establishments. This includes foreign establishments in which devices shipped to the United States are produced, as well as establishments located in the United States which produce devices for export.

To register establishments, producers should obtain from an EPA regional office the Application for Registration of Pesticide-Producing Establishments (EPA Form 3540-8). The applications require such information as the name and address of the company headquarters and the names and addresses of all device-producing establishments owned and operated by the company. This application must be submitted to the regional office on or before January 18, 1976. Upon receipt of a completed application, the regional office shall register each establishment listed and shall assign each establishment an EPA establishment number. This EPA establishment number must be displayed on all devices released for shipment by the establishment after 90 days after the producer is notified of the assigned number.

The production reports (EPA Form 3540-16) must be submitted to the regional office within thirty days after notification of registration and by February 1 each year thereafter.

C. *Section 8, Books and Records (7 U.S.C. 136f).* On September 18, 1974, regulations (40 CFR Part 169) for the implementation of section 8, Books and Records, were published in the FEDERAL REGISTER (39 F.R. 33512). Pursuant to the authority of section 8(a) of the Act, these regulations (at 40 CFR 162.2) specify those records pertaining to development, testing, production, holding, and distribution, which all producers of devices declared subject to the Act are required to maintain and submit to inspection. These requirements apply to domestic and foreign persons producing devices for sale and distribution in the United States and to domestic producers who export devices.

Specifically, producers of devices subject to the Act are required to maintain the following records:

169.2(b): Records showing the brand names and quantities of devices produced. These records shall be retained for two years.

169.2(c): Records showing the following information regarding the receipt of devices: (1) Brand name of device, (2) Name and address of shipper, (3) Name of delivering carrier, (4) Date received, and (5) Quantities received.

These records shall be retained for two years.

169.2(d): Records showing the following information regarding the shipment of devices: (1) Brand name of device, (2) Name and address of the consignee, (3) Name of originating carrier, (4) Date shipped or delivered for shipment, and (5) Quantities shipped or delivered for shipment.

These records shall be retained for two years.

169.2(e): Inventory records with respect to the types and amounts of devices in stock which he has produced. These records may be disposed of when a more current inventory record is prepared.

169.2(h): In the case of devices intended solely for export to any foreign country, copies of the specifications or directions of the foreign purchaser for the production of the devices. These records shall be retained for two years after expiration of the contract.

Pursuant to the authority of section 8(b) of the Act, 40 CFR 169.3(b) requires that distributors, carriers, dealers or other persons who sell or deliver (or offer to sell or deliver) devices declared subject to the Act, allow inspection of the records they have pertaining to the following:

(1) The delivery or holding of the device and quantity held; (2) Date of shipment and receipt; (3) Name and address of consignee and consignor; and (4) Any guarantees received pursuant to section 12(b)(1).

D. *Section 17, Imports and Exports (7 U.S.C. 136o).* On August 1, 1975, regulations (19 CFR Part 12.1) for the implementation of section 17, Imports and Exports, were published in the FEDERAL REGISTER (40 FR 32321). These regulations require that devices produced by foreign manufacturers and imported into the United States comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices (EPA Form 3540-1, available at any EPA office) for review and determination as to whether the shipment should be sampled and/or permitted entry into the United States. The Act also provides that samples may be collected and examined and that shipments may be permitted entry, detained until brought into compliance, destroyed, or re-exported.

With respect to devices produced in this country for export, section 17(a) of the FIFRA as amended requires that such devices must be prepared or packed in accordance with the specifications or directions of the foreign purchaser and that producers of such devices must maintain books and records pursuant to section 8(a).

VI. ENFORCEMENT AUTHORITIES

Section 9(a) (7 U.S.C. 136(g)(a)) of the Act authorizes officers of the Agency to inspect any establishment or other place where a device is held for distribution or sale in order to obtain a sample of the device as packaged, labeled and released for shipment, and samples of any containers or labeling for the device. Officers of the Agency are also authorized

AR0000021

to inspect books and records required to be maintained under section 8(a) and copies of records which are available under section 8(b).

Pursuant to section 12(a)(2)(B) of the Act, it is unlawful for any person to refuse to keep or to permit inspection of books and records, or to refuse to permit inspection of an establishment. Pursuant to section 12(a)(1)(F) of the Act, it is unlawful to sell or distribute any device which is misbranded. Finally, pursuant to section 12(a)(2)(L) of the Act, it is unlawful to violate any provision of section 7.

Upon a finding of any unlawful act, the Administrator may assess a civil penalty pursuant to section 14(a) of the Act or initiate criminal proceedings pursuant to section 14(b) of the Act. If, upon inspection or tests, a device is believed to be in violation of the Act, or if it is believed that a device is intended to be distributed or sold in violation of the Act, a Stop Sale, Use or Removal Order may be issued pursuant to section 13(a). Additionally, section 13(b) authorizes in rem seizure proceedings in a federal district court against any device which is misbranded or which, when used in accordance with the requirements imposed under the Act causes unreasonable adverse effects upon the environment. Finally, the Administrator may seek injunctive relief pursuant to section 16(c) to prevent and restrain violations of the Act.

VII. Public Comment

The Administrative Procedure Act (5 U.S.C. 533(b)) provides that the solicitation of comments is not required of Federal agencies for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." EPA has determined that this Notice falls within this exemption from the requirement to solocit public comment. Nonetheless, interested persons may submit written comments regarding the policy set forth in this Notice to the Pesticides and Toxic Substances Enforcement Division (EN-342), Office of Enforcement, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Three copies of these comments should be submitted to facilitate the work of the EPA and others interested in inspecting such documents.

Dated: November 8, 1976.

Stanley W. Legro,
Assistant Administrator for Enforcement.

[FR Doc.76-34119 Filed 11-18-76;8:45 am]

[FRL 646-2; OPP-30114A]

PESTICIDE PROGRAMS

Approval of Application to Register Pesticide Product Containing A New Active Ingredient and Waiver of Data

On April 21, 1976, the Environmental Protection Agency (EPA) gave notice (41 FR 16692) that the United States Forest Service (USFS), 1205-B (RPE), 14th and Independence Ave. SW, Washington, D.C. 20250, had filed an application with the EPA to register the pesticide product TM BIOCONTROL-1 containing 3.5 percent of the active ingredient polyhedral inclusion bodies of Douglas Fir Tussock Moth nucleopolyhedrosis virus which was not previously registered at the time of submission. The application received from the USFS proposed that the product be used in aerial application to control Douglas Fir Tussock Moth and that the product be classified for general use. PM17.

Having considered the evidence submitted by USFS in their application for registration and the data submitted in support thereof, the Administrator has made a written finding pursuant to the regulations (40 CFR 180.6(a)(3)) with respect to whether such properties of TM Biocontrol-1 are fundamentally different from the factors considered by EPA in establishing the data requirements set forth in the Registration Guidelines. Although the Guidelines were published as proposed rules in the Federal Register on June 25, 1975 (40 FR 26802), and have not as yet been promulgated in their final form, the basic data requirements set forth in the proposed Guidelines represent the data currently considered necessary to support the registration of a pesticide product. Accordingly, the notification of data waiver will apply to the supporting data now required by the Agency and set forth in the proposed Guidelines.

The Administrator has found that the submission of certain data is not necessary for determining whether TM Biocontrol-1 will generally cause unreasonable adverse effects on man or the environment. Specifically, the following required data have been waived by the Administrator for the polyhedral inclusion bodies of the nucleopolyhedrosis virus of the Douglas Fir Tussock Moth:

1. Avian 8-day dietary LC_{50} study utilizing a native upland game bird, preferably bobwhite quail.
2. Acute LC_{50} studies to 96 hours on a native cold and warm water species of fish, preferably utilizing trout and bluegill sunfish.
3. Acute aquatic invertebrate LC_{50} to 48 hours, preferably utilizing *daphnia sp.*

The primary basis of this waiver is due to the natural presence of the nucleopolyhedrosis virus in the environment and its role in bringing about the collapse of epizootic Douglas Fir Tussock Moth populations. During outbreaks of the Tussock Moth, large amounts of this virus are naturally released into the environment. Moreover, data presented by the registrant demonstrate that a much greater amount of this virus is released naturally into the environment through the collapse of Douglas Fir Tussock Moth populations than is released through the application of this product as a suppression measure.

Finally, it should be noted that this product can be used against only one pest, the Douglas Fir Tussock Moth, and that infestations of this pest are cyclic in nature; the maximum use of this product would likely be once in 6 to 10 years, and therefore exposure of fish and wildlife to this product would be minimal. Because the data submitted by the registrant have adequately demonstrated that this product is fundamentally different from the products for which the fish and wildlife testing requirements were designed, a waiver of the data listed above is both appropriate and acceptable.

This application was approved August 11, 1976, and the product has been assigned the EPA Registration No. 27586-1. Notice of registration is given in accordance with the regulations (40 CFR 180.7(d)(2)) for the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (*86 Stat. 973; 89 Stat. 751, 7 U.S.C. 136(a)* et seq.).

Test data and other information submitted in support of this registration as well as such other scientific information deemed relevant to the registration decision, except for such material protected by section 3(c)(1)(D) and section (10) of FIFRA, will be available for public inspection in the office of the Information Coordination Section, Technical Services Division (WH-569), Office of Pesticide Programs, Room EB-31, East Tower, 401 M St., Washington, D.C. 20460.

It is suggested that persons interested in viewing these data notify the Information Coordination Section, either by letter at the above address or by telephone at 202/426-2690, prior to visiting the EPA Headquarters Office so that clearance procedures may be instituted and the appropriate data made available for review purposes pursuant to the regulations for section 3(c)(2) of FIFRA (40 CFR 162.7(f)).

Dated: November 15, 1976.

Edwin L. Johnson,
Deputy Assistant, Administration for Pesticides Program.

[FR Doc.76-34120 Filed 11-18-76;8:45 am]

[FRL 647-2; OPP-30000/9]

PESTICIDE PROGRAMS

Intent to Process Pesticide Products for Reregistration—Sperm Whale Oil

The Deputy Assistant Administrator, Office of Pesticide Programs, Environmental Protection Agency (EPA) has determined that the use of pesticide products containing sperm whale oil which has already been stockpiled does not result in fatality to members of endangered species; accordingly, such product registrations will be returned to the Registration Division, Office of Pesticide Programs, for processing according to normal reregistration and classification procedures.

I. *Regulatory provisions.* On July 3, 1975 (40 FR 28242), EPA promulgated regulations (40 CFR 162) for the registration, reregistration, and classification of pesticides, pursuant to Section 3 of the Federal Insecticide, Fungicide and

AR0000022

FIFRA ENFORCEMENT RESPONSE POLICY

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

December 2009

FIFRA ENFORCEMENT RESPONSE POLICY

TABLE OF CONTENTS

I. INTRODUCTION 4

II. OVERVIEW OF THE POLICY 4

III. DETERMINING THE LEVEL OF ACTION 5

A. Notices of Warning 5

B. Notices of Detention (Section 17) 6

C. Stop Sale, Use, or Removal Orders (SSURO) 6
1. Issuance of a SSURO 7

D. Seizures 8

E. Injunctive Relief 9

F. Civil Administrative Penalties 9

G. Denials, Suspensions, Modifications, or Revocations of Applicator Certifications 11
1. Suspension 11
2. Denial/Revocation 12

H. Recalls 12
1. Cancelled and Suspended Products 12
a. Mandatory Recalls 12
b. Voluntary Recalls 13
2. Other Recalls 13

I. Criminal Proceedings 13
1. Parallel Criminal and Civil Proceedings 14

J. State and Federal Roles in Enforcement of FIFRA 15

K. Press Releases and Advisories 15

IV. ASSESSING ADMINISTRATIVE PENALTIES 15

A. Computation of the Penalty 15
1. Independently Assessable Violations 16
2. Size of Business 17
3. Gravity of the Violation 18
4. Base Penalty Amount 18

5. Adjustments for Case-Specific Factors....19
6. Economic Benefit of Noncompliance....20
a. Economic Benefit from Delayed Costs and Avoided Costs....21
b. Calculation of Economic Benefit from Delayed and Avoided Costs....21
c. Additional Information on Economic Benefit....23
7. Ability to Continue in Business/Ability to Pay....23

B. Modifications of the Penalty....25
1. Graduated Penalty Calculations....25
2. Voluntary Disclosure....26
3. Adjusting the Proposed Civil Penalty in Settlement....27
a. Factual Changes....27
b. Negotiations Involving Only the Amount of Penalty....27
i. Good Faith Adjustments....27
ii. Special Circumstances/Extraordinary Adjustments....27
iii. Supplemental Environmental Projects (SEPs)....28

APPENDICES

APPENDIX A - FIFRA VIOLATIONS AND GRAVITY LEVELS....29

APPENDIX B - GRAVITY ADJUSTMENT CRITERIA....34

APPENDIX C - SUMMARY OF TABLES....36

APPENDIX D - FIFRA CIVIL PENALTY CALCULATION WORKSHEET....38

APPENDIX E – ENFORCEMENT RESPONSE POLICY FOR FIFRA SECTION 7(c) – PESTICIDE PRODUCING ESTABLISHMENT REPORTING REQUIREMENTS (June 2007)....

APPENDIX F – FIFRA: WORKER PROTECTION STANDARD (WPS) PENALTY POLICY – INTERIM FINAL (September 1997)....

APPENDIX G – ENFORCEMENT RESPONSE POLICY FOR THE FIFRA GOOD LABORATORY PRACTICES (GLP) REGULATIONS (September 1991)....

I. INTRODUCTION

This document sets forth guidance for the U.S. Environmental Protection Agency (EPA or the Agency) to use in determining the appropriate enforcement response and penalty amount for violations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).[1] The goal of this Enforcement Response Policy (ERP) is to provide fair and equitable treatment of the regulated community, predictable enforcement responses, and comparable penalty assessments for comparable violations. The policy is designed to allow swift resolution of environmental problems and to deter future violations of FIFRA by respondents, as well as other members of the regulated community.

This policy supersedes the "Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)" issued on July 2, 1990 and other FIFRA penalty policies, except for the following policies, which remain in effect: the June 2007 "Enforcement Response Policy for FIFRA Section 7(c), Pesticide Producing Establishment Reporting Requirement"; the September 1997 "FIFRA: Worker Protection Standard (WPS) Penalty Policy – Interim Final"; and the September 1991 "Enforcement Response Policy for the FIFRA Good Laboratory Practices (GLP) Regulations." These policies are to be used as supplements to this policy to determine the appropriate enforcement response for the referenced programs. We have attached these policies as appendices to this document for ease of use.

This guidance applies only to violations of EPA's civil regulatory programs. It does not apply to enforcement pursuant to criminal provisions of laws or regulations that are enforced by EPA. The procedures set forth in this document are intended solely for the guidance of government professionals. They are not intended and cannot be relied on to create rights, substantive or procedural, enforceable by any party in litigation with the United States. The Agency reserves the right to act at variance with this policy and to change it at any time without public notice.

II. OVERVIEW OF THE POLICY

This Enforcement Response Policy is divided into three main sections. The first section, "Determining the Level of Action," describes the Agency's options for responding to violations of FIFRA. The second section, "Assessing Civil Administrative Penalties," elaborates on EPA's policy and procedures for calculating civil penalties to be assessed in administrative cases against persons who violate FIFRA. The third section, the appendices, contains tables to be used in calculating civil penalties for this ERP and the other FIFRA penalty policies that remain in effect. The appendices to this ERP are: (1) Appendix A - FIFRA Violations and Gravity Levels; (2) Appendix B - Gravity Adjustment Criteria; (3) Appendix C - The Summary of Tables; (4) Appendix D - The FIFRA Civil Penalty Calculation Worksheet; (5) Appendix E - "Enforcement Response Policy for FIFRA Section 7(c), Pesticide Producing Establishment Reporting Requirement" (June 2007); (6) Appendix F – "FIFRA: Worker Protection Standard (WPS) Penalty Policy – Interim Final" (September 1997); and Appendix G – Enforcement Response Policy for the FIFRA Good Laboratory Practices (GLP) Regulations.

---

[1] For purposes of this Policy and its Appendices, the terms "pesticide" and "pesticide product" include, as applicable, "pesticide," "antimicrobial pesticide," "device," "pesticide product," "pesticidal substance," and/or "plant incorporated protectant" as these terms are defined and used in FIFRA § 2(u), (mm), and (h), and 40 C.F.R. Parts 152 - 174.

III. DETERMINING THE LEVEL OF ACTION

Once the Agency finds that a FIFRA violation has occurred, EPA will need to determine the appropriate level of enforcement response for the violation. FIFRA provides EPA with a range of enforcement options. These options include:

-- Notices of Warning under sections 9(c)(3), 14(a)(2), and 14(a)(4);

-- Notices of Detention under section 17(c);

-- Stop Sale, Use, or Removal Orders under section 13(a);

-- Seizures under section 13(b);

-- Injunctions under section 16(c);

-- Civil administrative penalties under section 14(a);

-- Denials, suspensions, modifications, or revocations of applicator certifications under 40 C.F.R. Part 171;

-- Referral for criminal proceedings under section 14(b); and

-- Recalls.

To ensure national consistency in FIFRA enforcement actions, EPA enforcement professionals should use this ERP as a guide in considering the facts and circumstances of each case and the company's compliance history to ensure an enforcement response appropriate for the particular violations. Each of the potential enforcement responses is discussed below.

A. Notices of Warning

FIFRA §§ 14(a)(2), 14(a)(4), and 9(c)(3) provide EPA with the authority to respond to certain violations of FIFRA with a Notice of Warning (NOW) to the violator. Under FIFRA § 14(a)(2), EPA may not assess a penalty for violations by a private applicator or other person not covered by section 14(a)(1) without having issued a written warning or citation for a prior violation of FIFRA by that person, "except that any applicator not included [in paragraph 14(a)(1)] who holds or applies registered pesticides, or uses dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served . . . may be assessed a civil penalty . . . of not more than $500 for the first offense nor more than $1,000 for each subsequent offense." For all persons not covered by the exception in section 14(a)(2), EPA should issue a Notice of Warning for a first-time violation.

A state citation for a violation that would also be considered a violation under FIFRA, can be used to meet the requirement of a citation for a prior violation under FIFRA § 14(a)(2). For this purpose, the prior citation may be a notice of warning and does not have to include a penalty. The prior citation does not have to be related to the current violation; it may be for any FIFRA violation.

Regions may issue a NOW or assess a penalty of up to $500[2] for the first offense by any applicator within the scope of the exception set forth in section 14(a)(2). Section 9(c)(3) permits EPA to issue a written Notice of Warning for minor violations of FIFRA in lieu of instituting a penalty action if the Administrator believes that the public interest will be adequately served by this course of action. Generally, a violation will be considered minor under this section if the total "gravity adjustment value," as determined from Appendix B of this ERP, is three or less. A Notice of Warning may also be appropriate for certain first-time recordkeeping violations as listed in Appendix A (for example, late Section 7 reports that meet the guidelines of the FIFRA Section 7 ERP). FIFRA § 14(a)(4) provides that EPA may choose to issue a Notice of Warning in lieu of a penalty action if EPA determines that the violation occurred despite the exercise of due care or the violation did not cause significant harm to health or the environment.

B. Notices of Detention

A shipment of a pesticide or device may not be imported into the United States until EPA makes a determination of the admissibility of that shipment. FIFRA § 17 authorizes EPA to refuse admission of a pesticide or device into the United States if EPA determines that the pesticide or device violates any provisions of the Act. EPA may deny entry of a pesticide or device by refusing to accept the Notice of Arrival or by issuing a Notice of Detention and Hearing. Upon receiving a copy of the Notice of Detention, the Department of Homeland Security, through the U.S. Customs and Border Protection (Customs), will refuse delivery to the consignee. If the consignee has neither requested a hearing nor exported the pesticide or device within 90 days from the date of the notice, Customs will oversee destruction of the pesticide or device.

Customs regulations for enforcement of FIFRA § 17(c) (19 C.F.R. Part 12.110 - 12.117) allow Customs to release a shipment to the importer or the importer's agent before EPA inspects the shipment only if (1) the Customs District Director receives a completed Notice of Arrival signed by EPA indicating the shipment may be released and (2) the importer executes a bond in the amount of the value of the pesticide or device, plus duty. When a shipment of pesticides is released under bond, the shipment may not be used or otherwise disposed of until the Administrator has determined the admissibility of that shipment. Should the shipment subsequently be refused entry and the importer or agent fails to return the pesticide or device, the bond is forfeited.

C. Stop Sale, Use, or Removal Orders (SSURO)

FIFRA § 13 provides EPA the authority to issue a Stop Sale, Use, or Removal Order (SSURO) to any person who owns, controls, or has custody of a pesticide or device, whenever EPA has reason to believe on the basis of inspection or tests that:

(1) a pesticide or device is in violation of any provision of the Act;

(2) a pesticide or device has been, or is intended to be, distributed in violation of the Act; or

(3) the registration of a pesticide has been cancelled by a final order or has been suspended.

---

[2] Each of the FIFRA penalty amounts referenced in this document has been increased pursuant to the Debt Collection Improvement Act of 1996, which requires federal agencies to periodically adjust the statutory maximum penalties to account for inflation. The inflation adjustment is based on the date of the violation. See 40 C.F.R. Part 19.

EPA should generally seek a civil penalty in addition to the SSURO when EPA confirms that a violation of FIFRA has occurred. EPA has established criteria to ensure judicious use of the authority to stop the sale or use of a pesticide and to order its removal. SSUROs can be a useful enforcement response, particularly for more serious violations and situations that pose a significant risk, as described further below.

1. Issuance of a SSURO

A SSURO is among the most expedient and effective remedies available to EPA in its efforts to prevent illegal sale, distribution, and use of pesticides. Unlike a seizure, EPA does not need to bring action in federal court and does not need to take custody of the materials. The advantages of a SSURO over other responses are that: (1) it may be issued whenever EPA has *reason to believe* that the product is in violation of the Act; (2) it is easier to prepare and issue than a seizure; (3) it governs all of the product under the ownership, custody, or control of the individual receiving the SSURO regardless of where the product is located; (4) it can be written to include future amounts of the product that may come into custody of the respondent; and (5) it can easily be adapted to particular circumstances.

EPA should issue a SSURO against persons who own, control, or have custody of pesticides in the following categories:

-- Pesticides for which there is reason to believe that there is a potential hazard to human health or the environment because they are either not registered or are over-formulated, under-formulated, or adulterated as to present a potentially serious health hazard.[3]

-- Pesticides or devices with labeling that is materially misleading or fraudulent and, if followed by a user, is likely to cause a significant health hazard or serious adverse environmental effect. For example, a pesticide lacking a required restricted use label is an especially serious labeling violation. A SSURO should be issued for labeling on products that: (1) are ineffective for the purposes claimed; (2) are so chemically deficient as to affect the product's efficacy; or (3) bear false or misleading safety claims.

-- Pesticides or devices that are the subject of a recall in instances where the responsible party refuses to remove, is recalcitrant in removing, or is unable to remove the product from the channels of trade.

-- Pesticides or devices that are in violation of FIFRA and for which a civil penalty has been issued but the registrant has not brought the product into compliance.

-- Pesticides that have been suspended under FIFRA § 6.

EPA may also issue a SSURO if a product has been cancelled under any section of FIFRA or suspended under FIFRA §§ 4 or 3(c)(2)(B) and the existing stock deadlines have expired at that level of sale, distribution, or use. In addition, EPA may issue a SSURO to address serious violations that present a threat of harm where there has also been a large volume of sales.

---

[3] This may include pesticides packaged in improper or damaged containers, or pesticides that are so inadequately labeled as to make their safe or effective use unlikely or impossible.

When a SSURO is issued to a basic registrant for a registered pesticide product, the issuing office should ensure that the terms of the SSURO are equally applicable to the supplemental registrations of the product, as appropriate. In those cases, the SSURO should separately cite the supplemental registrations and copies should be sent to all known supplemental registrants.

D. Seizures

FIFRA § 13(b) gives EPA the authority to initiate *in rem* condemnation proceedings in U.S. District Court. Once a court grants EPA's request for authority to conduct a seizure, FIFRA § 9(b)(3) authorizes officers or employees designated by the Administrator to obtain and execute warrants for the purpose of seizing any pesticide or device that is in violation of the Act. Seizures may be executed with the assistance of the U.S. Marshals Service.

Under FIFRA § 13(b), EPA may initiate seizure actions in District Court against any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any state, or that is imported from a foreign country, if:

(1) a pesticide is adulterated or misbranded;
(2) a pesticide is unregistered;
(3) a pesticide has labeling that does not bear the information required by the Act;
(4) a pesticide is not colored or discolored as required;
(5) a pesticide bears claims or directions for use that differ from those made in connection with its registration;
(6) a device is misbranded; or
(7) a pesticide or device causes unreasonable adverse effects on the environment even when used in accordance with FIFRA requirements.

These circumstances are similar to the circumstances under which EPA would issue a SSURO. Because a SSURO is an administrative action, it can be issued more quickly than a seizure, which requires judicial action. The SSURO is therefore the more expedient enforcement response. Nevertheless, the Agency should consider initiating a seizure in the following circumstances:

- EPA has issued a SSURO but the recipient of the order has not complied with it;
- EPA has reason to believe that a person, if issued a SSURO, would not comply with it;
- The pesticide at issue is so hazardous that it should be removed from the marketplace, place of storage, or place of use to prevent any chance of harm to human health or the environment;
- The seizure will be used to support a recall; or
- It is necessary to dispose of products being held under a SSURO for which the responsible party has indicated it will not take corrective action.

E. Injunctive Relief

FIFRA § 16(c) gives EPA the authority to initiate actions in U.S. District Court seeking permanent injunction, preliminary injunction, or temporary restraining order. Because an injunction is an extraordinary form of relief, the Agency's arguments supporting injunction must be clear and compelling. As a party seeking permanent injunction, EPA would need to demonstrate one of the following: (1) other remedies would be inadequate or not available administratively either in restraining the violation or in preventing unreasonable risk to human health or the environment; (2) the Agency has already diligently exercised all appropriate administrative remedies (such as SSUROs and civil penalties) yet the violation or threat of violation continues unabated; or (3) irreparable injury, loss, or damage will result if the relief sought is not granted.

When seeking a preliminary injunction or temporary restraining order, the U.S. must demonstrate that: (1) immediate and irreparable injury, loss, or damage will result if the requested relief is not granted; and (2) EPA is likely to prevail at trial, based on the facts before the court.

Under FIFRA, a number of specific circumstances may justify injunctive relief. These include:

- Violation of a Section 6 suspension or cancellation order;
- Violation of a SSURO where a civil penalty or criminal prosecution would not provide a timely or effective remedy to deter further violations;
- Continued production, shipment, sale, distribution, or use of an unregistered pesticide after the Agency has taken civil or criminal action;
- A person continues to sell, distribute, or make available for use a restricted use pesticide (RUP) other than in accordance with FIFRA § 3(d), after the Agency has taken an enforcement response;
- A person continues to violate the FIFRA § 17 import or export requirements after the Agency has taken an enforcement response;
- A person continues to use a pesticide in a manner inconsistent with its labeling, in a manner contrary to an experimental use permit, or repeats any violation of FIFRA, after EPA has taken an enforcement response.

F. Civil Administrative Penalties

A civil penalty is the preferred enforcement response for most violations. A civil penalty is appropriate where the violation:

(1) presents an actual or potential risk of harm to humans or the environment,[4] or would impede EPA's ability to fulfill the goals of the statute; and
(2) was apparently committed as a result of ordinary negligence (as opposed to criminal negligence), inadvertence, or mistake; and the violation either:
(a) involves a violation by any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor, or any applicator within the scope of the exception set forth in FIFRA § 14(a)(2) (no prior warning is required by FIFRA for violators in this category); or
(b) involves a private applicator or other person not listed above who has received a prior Notice of Warning or citation for a FIFRA violation (as described in section III.A).

FIFRA § 14(a)(1) provides that a registrant, commercial applicator, wholesaler, dealer, or other distributor may be assessed a civil penalty of up to $5,000 for each violation. FIFRA § 14(a)(2) authorizes the Administrator to assess a private applicator or other person a penalty of up to $1,000 for each violation occurring after the issuance of a Notice of Warning or a citation for a prior FIFRA violation. Additionally, any applicator within the scope of the exception set forth in FIFRA § 14(a)(2) may be assessed a civil penalty of up to $500 for the first offense, and up to $1,000 for each subsequent offense.

Each of these penalty amounts has been increased pursuant to the Debt Collection Improvement Act of 1996, which requires federal agencies to periodically adjust the statutory maximum penalties to account for inflation. EPA has thus increased the maximum penalty amounts for FIFRA violations. For violations of FIFRA § 14(a)(1) that occur on or after January 12, 2009, the maximum civil penalty has increased to $7,500 for each violation. Violations prior to that date may be assessed up to $6,500 for each violation. For violations of FIFRA § 14(a)(2) that occur on or after January 12, 2009, the maximum civil penalty has increased to $1,100 for each violation following the first offense by both private applicators and any applicator within the scope of the exception set forth in FIFRA § 14(a)(2). Additional penalty inflation increases are expected to occur periodically and such increases are incorporated by reference into this ERP.

As the statutory definitions of "distribute or sell" and "commercial applicator" indicate, and as the conference report for the Federal Pesticide Act of 1978[5] confirms, any applicator, including a "for hire" applicator, who holds or applies an unregistered pesticide to provide a service of controlling pests without delivering any unapplied pesticide, will be considered a distributor of pesticides and will be subject to the higher penalties set forth in FIFRA § 14(a)(1) and 14(b)(1). Any applicator, other than a private applicator, who uses or supervises the use of a restricted use pesticide (RUP), whether or not that applicator is certified, is a commercial applicator and is subject to the higher penalties set forth in section 14(a)(1) and 14(b)(1). Any applicator, including a certified applicator, who holds or applies a general use pesticide (GUP) or an unclassified pesticide in violation of FIFRA will be subject to the lower penalties set forth in section 14(a)(2) and 14(b)(2).

---

[4] In such cases, the Agency should consider issuing a SSURO or other injunctive relief in addition to a civil penalty.
[5] Senate Report No. 95-1188, September 12, 1978, pp. 44 and 45.

G. Denials, Suspensions, Modifications, or Revocations of Applicator Certifications

Regulations governing certification of pesticide applicators (40 C.F.R. Part 171) authorize EPA to deny, suspend, or revoke a federally issued applicator certification if the holder of the certification violates FIFRA or its regulations. The Agency views enforcement actions affecting certification status as a very strong measure, to be taken only when the "public health, interest, or welfare warrants immediate action," 40 C.F.R. § 171.11(f)(5)(i). Therefore, EPA will deny, suspend, modify, or revoke a federal certification only in response to serious violations or against persons with a history of noncompliance.

1. Suspension

In response to violations by applicators that have previously received a civil complaint for FIFRA violations and where none of the factors for revocation (discussed in paragraph G.2. below) are present, EPA will seek suspension of the individual applicator's federal certification, as well as assess a civil penalty against the employer. EPA may also suspend certifications of commercial applicators who violate restricted use pesticides recordkeeping requirements, 40 C.F.R. § 171.11(c)(7); 40 C.F.R. § 171.11(f)(1)(iii). For purposes of this section of the policy, EPA will not distinguish between commercial and private applicators. A suspension has a more substantial impact on commercial applicators because it affects their primary business activity. Recommended suspension periods are set forth on the chart below.

Recommended Suspension Periods

	First enforcement action	**Second enforcement action**[6]	**Third enforcement action**
Enforcement remedy	Penalty action	Penalty action	Penalty action
Base suspension period	N/A	4 months	6 months
Additional suspension time for multiple violations	N/A	2 months for each additional violation (up to a limit of 8 months total)	2 months for each additional violation (up to a limit of 12 months total)

If EPA decides to suspend certification, it must notify the applicator of the grounds upon which the suspension is based and the time period during which the suspension will be in effect. In order for the suspension to function as a deterrent, the suspension should take effect during the time when the applicator is most likely to be applying restricted use pesticides. In cases where the violation involved keeping fraudulent records (*i.e.*, where the violator intentionally concealed or misrepresented the true circumstances and the extent of the use of restricted use pesticides), EPA may revoke the violator's certification in response to the initial infraction.

[6] For purposes of this section, the second and third enforcement actions must occur within five years of the original civil administrative complaint.

2. Denial/Revocation

The denial or revocation of a certification deprives an applicator of the authority to apply restricted use pesticides and forces the applicator to acquire or re-acquire certification. EPA will not consider an application to acquire or re-acquire certification for at least six months following a denial or revocation. Therefore, EPA will deny or revoke a certification only where:

(1) a violation resulted in a human fatality or created an imminent danger of a fatality;
(2) a violation resulted in severe damage to the environment or created an imminent danger of severe damage to the environment;
(3) a misuse violation has resulted in significant contamination of food and water;
(4) the violator's certification has been suspended as a result of a previous serious violation;
(5) the violator's certification has been suspended three times within the past five years; or
(6) a person has maintained or submitted fraudulent records or reports.

If EPA pursues an action to deny, revoke, or modify an applicator's certification, EPA will notify the applicant or federal certificate holder of:

(1) the ground(s) upon which the denial, revocation, or modification is based;
(2) the time period during which the denial, revocation, or modification is effective, whether permanent or otherwise;
(3) the conditions, if any, under which the individual may become certified or recertified; and
(4) any additional conditions EPA may impose.

EPA must also provide the federally certified applicator an opportunity to request a hearing prior to final Agency action to deny, revoke, or modify the certificate.

H. Recalls

1. Suspended or Cancelled Products

FIFRA § 19(b) gives EPA the authority to recall pesticide products if the registration of a pesticide has been suspended and cancelled and EPA finds that a recall is necessary to protect public health or the environment. Where the product registration has been suspended or cancelled, EPA will request either a voluntary or mandatory recall. When EPA believes that a recall is necessary to protect public health or the environment and the product registration has not been suspended or cancelled, EPA may request an informal recall, which is also voluntary.

EPA should only request a recall where the evidence clearly supports the need for such action. EPA will base the decision that a product should be withdrawn from the market on information in the sample file, including laboratory analyses, staff evaluations and opinions, and other available information. All information supporting a recall decision should be included in the official file.

a. Mandatory Recalls

If a product is suspended and cancelled, a voluntary recall by the registrant and others in the chain of distribution may be sufficient. However, if the Agency believes that a voluntary recall will not ensure protection of human health or the environment, mandatory recall procedures under FIFRA §§ 19(b)(3) and (4) can be used to require registrants, distributors, or

sellers of a cancelled pesticide to:

(1) recall the pesticide;
(2) make available storage facilities to accept and store existing stocks of the suspended and cancelled pesticide;
(3) inform the EPA of the location of the storage facility;
(4) inform the EPA of the progress of the recall;
(5) provide transportation of the pesticide on request; and
(6) take reasonable steps to inform holders of the recall and transportation provisions.

Persons conducting the recall must comply with transportation, storage, and disposal requirements set forth in the recall plan developed and approved under FIFRA § 19(b).

b. Voluntary Recalls

Recalls other than those described in section 1.a., above, are voluntary. A voluntary recall is appropriate if EPA finds that it can be "as safe and effective as a mandatory recall." Voluntary recalls can be used where the cancelled product is either potentially hazardous when used as directed, ineffective for the purposes claimed, or significantly violative in nature. For a voluntary recall, EPA will ask the registrant to develop a recall plan. The effectiveness of these recalls depends on the cooperation of the company involved. The company may seek EPA's assistance in developing or implementing a recall plan, but it is not required to do so.

2. Other Recalls

A product does not have to be suspended or cancelled for EPA to request a recall. The Agency should consider asking the company to do an informal recall of a product when its use as directed by the label is likely to result in:

(1) injury to the user or handler of the product;
(2) injury to domestic animals, fish, wildlife, or plant life;
(3) physical or economic injury because of ineffectiveness or due to the presence of actionable residues; or
(4) identifiable adverse effects on the environment.

For example, EPA may issue an informal recall for an antimicrobial product that fails efficacy testing for a public health organism when the product is distributed to hospitals or other health care facilities.

In cases posing more serious threats, the Agency may monitor the progress of an informal recall and may ask the company to submit progress reports and to notify state officials to ensure that the recall occurs. These informal recalls are generally accompanied by a civil penalty action or a SSURO. In cases where a recall is necessary but the level of potential hazard is not great or when it is unlikely that significant amounts of the defective product remain in the marketplace, the recall may be conducted entirely by the company with no monitoring by EPA or state officials.

I. Criminal Proceedings

FIFRA § 12 specifically lists the unlawful acts that are subject not only to civil and administrative enforcement but also to criminal enforcement. (For further information on criminal enforcement investigations see Chapter 18 of the Pesticides Inspection Manual, "FIFRA

Criminal Enforcement.") Section 14(b) provides the authority to proceed with criminal sanctions against violators, as follows.

- A registrant, applicant for a registration, or producer who knowingly violates the Act is subject, upon conviction, to a fine of not more than $50,000 or imprisonment for up to one year, or both.

- A commercial applicator of a restricted use pesticide, or any other person not described above who distributes or sells pesticides or devices, who knowingly violates the Act is subject, upon conviction, to a fine of not more than $25,000 or imprisonment for up to one year, or both.

- A private applicator or other person not included above who knowingly violates the Act is subject, upon conviction, to a fine of not more than $1,000, or imprisonment for not more than 30 days, or both.

FIFRA § 14(b)(1) and (2) include the requirement that the violation be committed "knowingly." An act is committed "knowingly" by a person who has the general intent to do the action(s) constituting the violation. A specific intent to violate FIFRA or knowledge of its regulations is not a necessary element of the crime. Thus, the government must generally prove that the defendant knew of the conduct that constituted the violation and that the person's action(s) was voluntary and intentional and not the result of an accident or mistake of fact.

In addition, pursuant to the Alternative Fines Act (18 U.S.C. § 3571), the FIFRA criminal fine amounts for an individual or an organization[7] may be substantially increased if the violation results in death. All acts of the regulated community exhibiting actual or suspected criminal conduct should be discussed with EPA's regional or Headquarters Criminal Enforcement Counsel or brought to the attention of the Criminal Investigation Division (CID) for possible investigation.

1. Parallel Criminal and Civil Proceedings

Although the majority of EPA's enforcement actions are brought as either a civil action or a criminal action, there are instances when it is appropriate to bring both a civil and a criminal enforcement response. These include situations where the violations merit the deterrent and retributive effects of criminal enforcement, yet a civil action is also necessary to obtain an appropriate remedial result, and where the magnitude or range of the environmental violations and the available sanctions make both criminal and civil enforcement appropriate.

Active consultation and cooperation between EPA's civil and criminal programs, in conformance with all legal requirements including OECA's Parallel Proceedings Policy (September 24, 2007), is critical to the success of EPA's overall enforcement program. The success of any parallel proceedings depends upon coordinated decisions by the civil and criminal programs as to the timing and scope of their activities. For example, it will often be important for the criminal program to notify civil enforcement managers that an investigation is about to become overt or known to the subject. Similarly, the civil program should notify the criminal

[7] As used in Title 18 of the United Sates Code, the term "organization" means a person other than an individual.

program when there are significant developments that might change the scope of the relief. In every parallel proceeding, communication and coordination should be initiated at both the staff and manager levels and should continue until resolution of all parallel matters.

J. State and Federal Roles in Enforcement of FIFRA

State governments have primary enforcement authority for both civil and criminal pesticide use violations under FIFRA §§ 26 and 27. States are allowed 30 days to commence appropriate enforcement actions for such violations. While Congress delegated to the states primary enforcement authority for pesticide use violations, FIFRA does not create exclusive enforcement jurisdiction in the states. A state may waive its primary enforcement responsibility or make a referral to the United States for federal action.

EPA has primary enforcement authority over violations concerning the sale or distribution of pesticides. Examples of such violations include failure to report a pesticide's unreasonable adverse effects on the environment, distribution of an unregistered pesticide, violations of a cancellation order or an EPA SSURO, and fraudulent labeling, advertising, or registration of a pesticide. FIFRA violations that are not use violations may be investigated and prosecuted on the federal level without waiting for state authorities to exercise their enforcement responsibility. Under most circumstances EPA will inform the state of an EPA investigation being conducted within its borders.

K. Press Releases and Advisories

EPA may, at its discretion, issue a press release or advisory to notify the public of the filing of an enforcement action, settlement, or adjudication concerning a person's violation of FIFRA. A press release can be a useful tool to notify the public of Agency actions for FIFRA noncompliance and to educate the public on the requirements of FIFRA. Some regions routinely issue press releases to inform the public of FIFRA settlements. Issuance of a press release or advisory must not be an item of negotiation during settlement.

IV. ASSESSING CIVIL ADMINISTRATIVE PENALTIES

A. Computation of the Penalty

In determining the amount of a civil penalty, FIFRA § 14(a)(4) requires EPA to consider the appropriateness of the penalty to the size of respondent's business, the effect of the penalty on respondent's ability to continue in business, and the gravity of the violation.

For each type of violation associated with a particular product, the penalty amount is determined in a seven-step process considering the Section 14(a)(4) criteria listed above. These steps are:

(1) determine the number of independently assessable violations [Section IV.A.1. Independently Assessable Violations];

(2) determine the size of business category for the violator, using Table 1 [Section IV.A.2. Size of Business];

(3) determine the gravity of the violation for each independently assessable violation using Appendix A [Section IV.A.3. Gravity of Violation];

(4) determine the "base" penalty amount associated with the size of business (Step 2) and the gravity of violation (Step 3) for each independently assessable violation, using the matrices in Table 2 [Section IV.A.4. Base Penalty Amount];

(5) determine the "adjusted" penalty amount based on case-specific factors using the Gravity Adjustment Criteria in Appendix B and Table 3 [Section IV.A.5. Adjustment for Case-Specific Factors];

(6) calculate the economic benefit of noncompliance [Sections IV.A.6. Economic Benefit of Noncompliance]; and

(7) consider the effect that payment of the total penalty amount plus economic benefit of noncompliance derived from the above calculation will have on the violator's ability to continue in business [Section IV.A.7 Ability to Continue in Business/Ability to Pay].

A civil penalty may be further modified in accordance with Section IV.B.1. Graduated Penalty Calculations, Section IV.B.2. Voluntary Disclosure, and Section IV.B.3. Adjusting the Proposed Civil Penalty in Settlement.

1. Independently Assessable Violations

A separate civil penalty, up to the statutory maximum, will be assessed for each independent violation of the Act. A violation is considered independent if it results from an act (or failure to act) which is not the result of any other violation for which a civil penalty is to be assessed or if at least one of the elements of proof is different from any other violation.

Consistent with the above criteria, the Agency considers violations that occur from each sale or shipment of a product (by product registration number, not individual containers) or each sale of a product to be independent violations.[8] There may also be situations where two unlawful acts arise out of one sale or shipment, such as the sale of a product that is both a misbranded pesticide and an unregistered pesticide. Similarly, under the pesticide use regulations, one application of a pesticide may lead to multiple misuse violations. For example, if an applicator mixes pesticides over the rate prescribed by the label and during the same application allows pesticide to drift onto non-target areas, each of those acts would be a separately assessable violation of FIFRA § 12(a)(2)(G).

Each of these independent violations of FIFRA is subject to civil penalties up to the statutory maximum. For example, when EPA can document that a registrant has distributed a misbranded product (one single EPA product registration number) in four separate shipments, EPA will allege four counts of selling or distributing a misbranded product. Similarly, when EPA can document that a registrant has shipped four separate misbranded products (four separate EPA product registration numbers) in a single shipment, EPA will plead four counts of selling or

[8] Independent violations which can be documented as both per sale and per shipment are to be calculated only as either per sale or per shipment, whichever is more appropriate based on the supporting documentation.

distributing a misbranded product. In use cases that EPA handles, the Agency will allege three misuse violations when a commercial applicator who misuses a restricted use product on three occasions (either three distinct applications or three separate sites). If a dealer sells a restricted use pesticide (RUP) to six uncertified persons, other than in accordance with FIFRA § 3(d), EPA will plead six violations of FIFRA.

On the other hand, the Agency will assess a penalty for one violation arising from a single event or action (or lack of action) that is an unlawful act under FIFRA for multiple reasons unless the event or action results in two unlawful acts for which at least one element of proof differs. For instance, a person can be assessed a civil penalty of up to the statutory maximum for the sale and/or distribution of an unregistered, cancelled or suspended pesticide under FIFRA § 12(a)(1)(A). If the unregistered pesticide is actually a product whose registration had been cancelled, EPA cannot allege two separate violations of FIFRA § 12(a)(1)(A) since the sale or distribution related to a single event or transaction. However, the Agency could separately allege a violation of a cancellation order under FIFRA § 12(a)(2)(K). In this example, the violation of the cancellation order is independent of the sale and distribution of the unregistered product.

Another example of a dependent violation is multiple misbrandings on a single product label. EPA may assess a count of misbranding each time that a misbranded product is sold or distributed. For example, a registrant who sells or distributes four distinct shipments of a misbranded pesticide product generally may be assessed four counts of misbranding.
If a single product label is misbranded in one way or ten ways, as defined by FIFRA § 2(q), it is still misbranding on a single product label and is considered a single violation of FIFRA § 12(a)(1)(E). Note, however, for pesticide use regulations, where the applicator fails to follow two label requirements, for example, does not follow the prescribed application rate and does not provide the prescribed personal protective equipment, there are two separate violations.

When a product label is grossly misbranded such that two or more misbrandings assigned Level 2 in Appendix A are present, the gravity level is adjusted upward to a Level 1 to address the seriousness of the misbranding.

2. Size of Business

In order to provide equitable penalties, civil penalties that will be assessed for violations of FIFRA will generally decrease as the size of the business decreases. Size of business is determined based on an individual's or a company's gross revenues from all revenue sources during the prior calendar year. If revenue data for the previous year appears to be unrepresentative of the general performance of the business or the income of the individual, an average of the gross revenues for the three previous years may be used. Further, the size of business and gross revenue figures are based on the corporate family rather than a specific subsidiary or division of the company which is involved with the violation (including all sites owned or controlled by the foreign or domestic parent company) unless the subsidiary or division is independently owned.

As shown in the FIFRA Civil Penalty Matrices in Table 2, the appropriateness of the penalty to the size of the respondent's business is based on three distinct size of business categories. Further, because gross revenues of persons listed in FIFRA § 14(a)(1) [registrants, commercial applicators, wholesalers, dealers, retailers, or other distributors] will generally be higher than gross incomes of persons listed in FIFRA § 14(a)(2) [private applicators and other

persons not listed in 14(a)(1)], the policy has separate size of business categories for Section 14(a)(1) persons and Section 14(a)(2) persons. The size of business categories for FIFRA § 14(a)(1) and Section 14(a)(2) violators are listed in Table 1. Revenue includes all revenue from an entity and all of the entity's affiliates. When no information of any kind is available concerning a respondent's size of business, the penalty should be calculated using the Category I size of business.

TABLE 1

For section 14(a)(1) violators, the size of business categories are:

I - over $10,000,000 a year
II - $1,000,000 - $10,000,000 a year
III - under $1,000,000 a year

For section 14(a)(2) violators, the size of business categories are:

I - over $1,000,000 a year
II - $300,000 - $1,000,000 a year
III - under $300,000 a year

3. Gravity of the Violation

The "gravity level" established for each violation of FIFRA is listed in Appendix A of this ERP. The level assigned to each violation of FIFRA represents an assessment of the relative severity of each violation. The relative severity of each violation considers the actual or potential harm to human health and the environment which could result from the violation and the importance of the requirement to achieving the goals of the statute. The gravity level, which is determined from the chart in Appendix A, is then used to determine a base penalty figure from the FIFRA Civil Penalty Matrices in Step 4 below. In Step 5, the dollar amount derived from the matrix can be adjusted upward or downward depending on the actual circumstances of each violation.

4. Base Penalty Amount

The size of business categories and gravity levels are broken out in the FIFRA Civil Penalty Matrices shown in Table 2. Each cell of the matrix represents the Agency's assessment of the appropriate civil penalty, within the statutory maximum, for each gravity level of a violation and for each size of business category. Because FIFRA imposes different statutory ceilings on the maximum civil penalty that may be assessed against persons listed in FIFRA Section 14(a)(1) and persons listed in Section 14(a)(2), this policy has separate penalty matrices for Section 14(a)(1) violators and Section 14(a)(2) violators.

With the exception of any applicator within the scope of the exception set forth in FIFRA § 14(a)(2), EPA will only use the Section 14(a)(2) penalty matrix for persons falling under FIFRA § 14(a)(2) who have previously been issued a Notice of Warning or prior citation.[9]

[9] FIFRA § 14(a)(2) states that private applicators are only subject to civil penalties after receiving a notice of warning or following a citation for a prior violation. A notice of warning or citation for a prior

When a civil penalty is the appropriate response for a first-time violation by any applicator within the scope of the exception set forth in FIFRA § 14(a)(2), EPA will seek the statutory maximum civil penalty. Subsequent violations will be assessed using the FIFRA § 14(a)(2) civil penalty matrix below.

TABLE 2

Civil Penalty Matrix for FIFRA § 14(a)(1)

	SIZE OF BUSINESS		
LEVEL OF VIOLATION	**I – over $10,000,000**	**II -- $1,000,000 - $10,000,000**	**III – under $1,000,000**
Level 1	$7,500	7,150	7,150
Level 2	7,150	5,670	4,250
Level 3	5,670	4,250	2,830
Level 4	4,250	2,830	1,420

Civil Penalty Matrix for FIFRA § 14(a)(2) [10]

	SIZE OF BUSINESS		
LEVEL OF VIOLATION	**I – over $1,000,000**	**II -- $300,000 - $1,000,000**	**III – under $300,000**
Level 1	$1,100	1,100	1,100
Level 2	1,100	1,030	770
Levels 3 & 4	1,030	770	650

5. Adjustments for Case-Specific Factors

The Agency has assigned adjustments, based on the gravity adjustment criteria listed in Appendix B, for each violation relative to the specific characteristics of the pesticide involved, the harm to human health and/or harm to the environment, compliance history of the violator,

---

violation may include an action by either EPA or a delegated state if the prior violation would be a violation of federal law.

[10] This 14(a)(2) matrix is only for use in determining civil penalties issued subsequent to a notice of warning or following a citation for a prior violation, or in the case of a "for hire" applicator using a registered general use pesticide, subsequent to the issuance of a prior civil penalty.

and the culpability of the violator. Then the gravity adjustment values from each gravity category listed in Appendix B are to be totaled. The dollar amount found in the matrix will be raised or lowered, not to exceed the statutory maximum, based on the total gravity values in Table 3. Once this base penalty amount is calculated, it should be rounded to the nearest $100, in accordance with Amendments to Penalty Policies to Implement Penalty Inflation Rule 2008 - (Nakayama, 2008).[11]

TABLE 3

Total Gravity Value from Appendix B	**Enforcement Remedy**
3 or below	No action or Notice of Warning (60% reduction of matrix value recommended where multiple count violations exist)
4	Reduce matrix value 50%
5	Reduce matrix value 40%
6	Reduce matrix value 30%
7	Reduce matrix value 20%
8	Reduce matrix value 10%
9 to 11	Assess matrix value
12	Increase matrix value 10% **
13	Increase matrix value 20% **
14	Increase matrix value 30% **
15	Increase matrix value 40% **
16	Increase matrix value 50% **
17 or above	Increase matrix value 60% **
** Matrix value can only be increased to the statutory maximum.	

6. Economic Benefit of Noncompliance

The Agency's Policy on Civil Penalties (EPA General Enforcement Policy #GM-21), dated February 16, 1984, mandates the recapture of any significant economic benefit of noncompliance (EBN) that accrues to a violator from noncompliance with the law. Economic benefit can result from a violator delaying or avoiding compliance costs or when the violator realizes illegal profits through its noncompliance. A fundamental premise of the 1984 Policy is that economic incentives for noncompliance are to be eliminated. If, after the penalty is paid, violators still profit by violating the law, there is little incentive to comply. Therefore, enforcement professionals should always evaluate the economic benefit of noncompliance in calculating penalties. Note that economic benefit can only be added to the proposed penalty up to the statutory maximum penalty.

An economic benefit component should be calculated and added to the gravity-based penalty component when a violation results in "significant" economic benefit to the violator. "Significant" is defined as an economic benefit that totals more than $10,000 for all violations alleged in the complaint. In the interest of simplifying and expediting an enforcement action, enforcement professionals may use the "rules of thumb" (discussed in section 6.b below) to

[11] http://www.epa.gov/compliance/resources/policies/civil/penalty/amendmentstopenaltypolicies-implementpenaltyinflationrule08.pdf

determine if the economic benefit will be significant. Distribution and sale of unregistered and misbranded pesticides are examples of violations that are likely to result in significant economic benefits. For certain FIFRA requirements, the economic benefit of noncompliance may be relatively insignificant (e.g., failure to submit a report on time).

EPA generally will not settle cases for an amount less than the economic benefit of noncompliance. However, the Agency's 1984 Policy on Civil Penalties explicitly sets out three general areas where settling for less than the economic benefit may be appropriate. Since the issuance of the 1984 Policy, the Agency has added a fourth exception for cases where ability to pay is a factor. The four exceptions are:

- The economic benefit component is an insignificant amount (defined for purposes of this policy as less than $10,000);
- There are compelling public concerns that would not be served by taking a case to trial;
- It is unlikely, based on the facts of the particular case as a whole, that EPA will be able to recover the economic benefit in litigation; and
- The company has documented an inability to pay the total proposed penalty.

a. Economic Benefit from Delayed Costs and Avoided Costs

Delayed costs are expenditures that have been deferred by the violator's failure to comply with the requirements. The violator eventually will spend the money to achieve compliance. Delayed costs are either capital costs (i.e. equipment), if any, or one-time non-depreciable costs (e.g., registration fees for pesticides that are eventually registered).

Avoided costs are expenditures that will never be incurred, as in the case of an unlawfully distributed unregistered pesticide that is subsequently removed from commerce and never registered by the Agency. In this example, avoided costs include all the costs associated with product registration because the product was never registered. Those costs were never and will never be incurred. Those avoided costs might include the registration fees, annual maintenance fees, and costs associated with the testing that would have been required to support a pesticide registration or to support specific claims about the product.

b. Calculation of Economic Benefit from Delayed and Avoided Costs

Since 1984, it has been Agency policy to use either the BEN computer model or "rules of thumb" to calculate the economic benefit of noncompliance. The "rules of thumb" are straight-forward methods to calculate economic savings from delayed and avoided compliance expenditures. They are discussed more fully in the Agency's General Enforcement Policy #GM-22, entitled "A Framework for Statute-Specific Approaches to Penalty Assessments," issued on February 16, 1984, at pages 7-9. The "rule of thumb" methodology is available in a Lotus spreadsheet available to EPA enforcement professionals from the Special Litigation and Projects Division of the Office of Civil Enforcement. Enforcement professionals may use the "rules of thumb" whenever the economic benefit penalty is not substantial (generally under $10,000) and use of an expert financial witness may not be warranted. If the "rules of thumb" yield an amount

over $10,000, the case developer should use the BEN model and/or an expert financial witness to calculate the higher economic benefit penalty. Using the "rules of thumb," the economic benefit of delayed compliance may be estimated at: 5% per year of the delayed one-time capital costs, if any, and/or one-time non-depreciable costs for the period from the date the violation began until compliance was or is expected to be achieved. For avoided annual costs, the "rule of thumb" is the annual expenses avoided until the date compliance is achieved less any tax savings. These rules of thumb do not apply to avoided one-time or avoided capital costs. Enforcement professionals should calculate the economic benefit of avoided one-time and avoided capital costs, if any, by using the BEN model.

The primary purpose of the BEN model is to calculate economic savings for settlement purposes. The model can perform a calculation of economic benefit from delayed or avoided costs based on data inputs, including optional data items and standard values already contained in the program. Enforcement professionals wishing to use the BEN model should take the Basic BEN training course offered by the Special Litigation and Projects Division in cooperation with NETI. Enforcement professionals who have questions while running the model can access the model's help system which contains information on how to: use BEN, understand the data needed, and understand the model's outputs.

The economic benefit component should be calculated for the entire period for which there is evidence of noncompliance, i.e., all time periods for which there is evidence to support the conclusions that the respondent was violating FIFRA and thereby gained an economic benefit. Such evidence should be considered in the assessment of the penalty assessed for the violations alleged or proven, up to the statutory maximum for those violations. In certain cases, credible evidence may demonstrate that a respondent received an economic benefit for noncompliance for a period longer than the period of the violations for which a penalty is sought. In such cases, it may be appropriate to consider all of the economic benefit evidence in determining the appropriate penalty for the violations for which the respondent is liable. For example, in a case where credible evidence demonstrates that a respondent sold an unregistered pesticide during the past four years but the specific violations for which EPA has chosen to seek a penalty all occurred within the past two years, the economic benefit should be calculated for the four-year period. In such a case, the economic benefit component of the penalty for the specific sales transactions during the past two years should be based on a consideration of the economic benefit gained for the four-year period, but the total penalty is limited to the statutory maximum for the specific violations alleged and proven.[12]

In most cases, the violator will have the funds gained through non-compliance available for its continued use and/or competitive advantage until it pays the penalty. Therefore, for cases in which economic benefit is calculated by using BEN or by a financial expert, the economic benefit should be calculated through the anticipated date a consent agreement would be entered. If the matter goes to hearing, this calculation should be based on a penalty payment date corresponding with the relevant hearing date. It should be noted that the respondent will continue to accrue additional economic benefits after the hearing date, until the assessed penalty is paid. However, there are exceptions for determining the period of economic benefit when

[12]When considering the economic benefit of noncompliance that accrued to the respondent more than five years prior to the filing of a complaint or a pre-filing Consent Agreement, the litigation team should consult with the Waste and Chemical Enforcement Division.

using a "rule of thumb." In those instances, the economic benefit is calculated in the manner described in the first paragraph of this subsection.

c. Economic Benefit Gained from Illegal Sales of Unregistered Pesticides

In addition to delayed and avoided costs, an economic benefit may accrue to a violator of FIFRA from the sale of unregistered or misbranded pesticides. The economic benefit derived from sales of unregistered or misbranded pesticides is sometimes referred to as "illegal profits" or "illegal competitive advantage." Illegal profits economic benefit is fundamentally different from the economic benefit calculated by using the BEN model. Unlike the delayed/avoided benefits addressed through BEN, this type of economic benefit is based on the profits generated by violating the law. Care should be taken to insure that any calculation of a benefit derived from illegal profits does not include profits attributable to lawful operations of the facility or delayed or avoided costs already accounted for in the BEN calculation. In most cases, a violator will realize either benefits from delayed/avoided costs or from illegal profits; however, whenever the facts and circumstances of the case provide a sufficient basis to calculate illegal profits and the Region is able to obtain sufficient information, the Region should calculate the benefits due to illegal profits and add it to any other type of economic benefit that has been calculated.

7. Ability to Continue in Business/Ability to Pay

FIFRA § 14(a)(4) requires the Agency to consider the effect of the penalty on the respondent's ability to continue in business when determining the amount of the civil penalty. There are several sources available to assist enforcement professionals in determining a respondent's ability to pay. Enforcement professionals considering a respondent's ability to continue in business should consult "A Framework for Statute-Specific Approaches to Penalty Assessments," (cited above) and EPA General Enforcement Policy PT.2-1 (previously codified as GM-#56), entitled "Guidance on Determining a Violator's Ability to Pay a Civil Penalty" (December 16, 1986). In addition, the Agency has three computer models available to help assess whether violators can afford compliance costs and/or civil penalties: ABEL, INDIPAY and MUNIPAY. INDIPAY analyzes individual taxpayers' claims about inability to pay. MUNIPAY analyzes cities, towns, and villages' ability to pay. These models are designed for settlement purposes only.

ABEL is an EPA computer model that is designed to assess inability to pay claims from corporations and partnerships. The evaluation is based on the firm's excess cash flow. ABEL looks at the money coming into the entity, and the money going out. It then looks at whether the excess cash flow is sufficient to cover the firm's environmental responsibilities (i.e., compliance costs) and the proposed civil penalty. Because the program only focuses on a violator's cash flow, there are other sources of revenue that should also be considered to determine if a firm is unable to pay the full penalty. These include:

- Certificates of deposit, money market funds, or other liquid assets;
- Reduction in business expenses such as advertising, entertainment, or compensation of corporate officers;
- Sale or mortgage of non-liquid assets such as company cars, aircraft, or land;

- Related entities (e.g., the violator is a wholly owned subsidiary of Fortune 500 company).

The complaint will notify the respondent of its right under the statute to have EPA consider its ability to continue in business in determining the amount of the penalty. Any respondent may raise the issue of ability to pay/ability to continue in business in its answer to the complaint or during the course of settlement negotiations. If a respondent raises the inability to pay as a defense in its answer or in the course of settlement negotiations, the Agency should ask the respondent to present appropriate documentation, such as tax returns and financial statements. The respondent must provide records that conform to generally accepted accounting principles and procedures at its expense. If the proposed penalty exceeds the respondent's ability to pay, the penalty may be reduced to a level consistent with FIFRA § 14(a)(4). If a respondent does not provide sufficient information to substantiate its claim of inability to pay the calculated penalty, then EPA may draw an inference from available information that the respondent has the ability to pay the calculated penalty.[13]

A respondent may argue that it cannot afford to pay the proposed penalty even though the penalty as adjusted does not exceed EPA's assessment of its ability to pay. In such cases, EPA may consider a delayed payment schedule calculated in accordance with Agency installment payment guidance and regulations.[14] In exceptional circumstances, EPA may also consider further adjustment below the calculated ability to pay.

Finally, EPA will generally not collect a civil penalty that exceeds a violator's ability to pay as evidenced by a detailed tax, accounting, and financial analysis. However, it is important that the regulated community not choose noncompliance as a way of aiding financially troubled businesses. Therefore, EPA reserves the option, in appropriate circumstances, of seeking a penalty that might exceed the respondent's ability to pay, cause bankruptcy, or result in a respondent's inability to continue in business. Such circumstances may exist where the violations are egregious or the violator refuses to pay the penalty. However, if the case is generated out of an EPA regional office, the case file must contain a written explanation, signed by the regional authority duly delegated to issue and settle administrative penalty orders under FIFRA, which explains the reasons for exceeding the "ability to pay" guidelines. To ensure full and consistent consideration of penalties that may cause bankruptcy or closure of a business, the regions should consult with the Waste and Chemical Enforcement Division (WCED).[15]

---

[13] Note that under the Environmental Appeals Board ruling in *In re: New Waterbury*, LTD, *5* E.A.D. 529 (EAB 1994), in administrative enforcement actions for violations under statutes that specify ability to pay (which is analogous to ability to continue in business) as a factor to be considered in determining the penalty amount, EPA must prove it adequately considered the appropriateness of the penalty in light of all of the statutory factors. Accordingly, enforcement professionals should be prepared to demonstrate that they considered the respondent's ability to continue in business as well as the other statutory penalty factors and that their recommended penalty is supported by their analysis of those factors. EPA may obtain information regarding a respondent's ability to continue in business from the respondent, independent commercial financial reports, or other credible sources.

[14] *See*, 40 C.F.R. § 13.18.

[15] In accordance with the November 1, 1994 memorandum entitled, "Final List of Nationally Significant Issues and Process for Raising Issues to TPED." This final implementation guidance was developed in follow-up to Steve Herman's July 11, 1994 memorandum on "Redelegation of Authority and Guidance on Headquarters' Involvement in Regulatory Enforcement Cases."

B. Modifications of the Penalty

1. Graduated Penalty Calculations

In instances where inspectors or case developers obtain records which evidence multiple sales or distributions for the same violations, the Region may apply a "graduated" penalty calculation. The graduated method should only be applied after a consideration of the actual or potential serious or widespread harm caused by the violations, the toxicity of the pesticides involved, and the culpability of the violator. The graduated penalty method should not be used in cases involving highly culpable violators or violations that caused an actual serious or widespread harm to human health or the environment. In cases involving violations that present *potential* serious or widespread harm to human health or the environment, the Region should decide whether application of the graduated penalty method is appropriate based on the circumstances of the individual case.

In no case is the graduated penalty method mandated and the Agency maintains its statutory right to assess penalties of up to the statutory maximum for each violation, when appropriate. For highly culpable parties the penalty should be calculated at the full value for all violations. After considering the factors described above and determining that a graduated penalty method is appropriate, the Region may calculate the penalty in accordance with Table 4 below. Table 4 provides for three separate graduated systems based on the three "size of business" categories.

TABLE 4

Graduated Penalty Tables

Number of Distributions	CATEGORY I "SIZE OF BUSINESS" RESPONDENTS
1 – 100	100% of calculated per violation penalty
101 – 400	25% of per violation penalty
> 400	10% of per violation penalty

Number of Distributions	CATEGORY II "SIZE OF BUSINESS" RESPONDENTS
1 – 20	100% of calculated per violation penalty
21 – 40	25% of per violation penalty
> 40	10% of per violation penalty

Number of Distributions	CATEGORY III "SIZE OF BUSINESS" RESPONDENTS
1 – 5	100% of calculated per violation penalty
6 – 20	10 % of per violation penalty
> 20	5% of per violation penalty

Graduated penalties should generally be calculated separately for each type of violation and for each product (in other words, on a "per product violation" basis). In cases involving similar product violations (for example, violations involving products that contain the same

active ingredient and the same violative conduct on the part of the respondent), the Agency has the discretion to group together similar product violations for the graduated penalty calculation.

To calculate penalties using the graduated penalty method, the "adjusted" penalty amount must first be determined in accordance with Steps 1-5 of section IV.A Computation of the Penalty, above. The next step is to apply the graduated penalty calculation separately for each product violation, beginning with the first sale/distribution at 100% and proceeding to calculate the reduced penalty depending on the size of business. After the graduated penalty amount is calculated for each separate product violation, the Agency should add together the graduated penalty amounts for all of the product violations.

For example, a Category II business distributes two products with a total of three violations. For Product 1, the Agency is alleging misbranding (a Level 3 violation) and distribution of an unregistered pesticide (a Level 1 violation), each for 61 shipments. For Product 2, the Agency is alleging distribution of an unregistered pesticide (a Level 1 violation) for 90 shipments. After applying the case-specific factors, no adjustments to the base penalties were made. The graduated penalty calculation would proceed as follows:

Product 1, Misbranding (Level 3):

Violations 1-20 @ 100% =	20 violations @ $ 4,250 =	$ 85,000
Violations 21- 40 @ 25% =	20 violations @ $ 1,063 =	$ 21,260
Violations 41- 61 @ 10% =	21 violations @ $ 425 =	$ 8,925

Product 1, Unregistered (Level 2):

Violations 1-20 @ 100% =	20 violations @ $ 5,670 =	$113,400
Violations 21- 40 @ 25% =	20 violations @ $ 1,418 =	$ 28,360
Violations 41- 61 @ 10% =	21 violations @ $ 567 =	$ 11,907

Product 2, Unregistered (Level 2):

Violations 1-20 @ 100% =	20 violations @ $ 5,670 =	$113,400
Violations 21- 40 @ 25% =	20 violations @ $ 1,418 =	$ 28,360
Violations 41- 90 @ 10% =	50 violations @ $ 567 =	$ 28,350

When the graduated penalty method is applied to the example case, the penalty is $438,962, which is significantly lower than the $1,115,420 [(61 x 4,250) + (61 x 5,670) + (90 x 5, 670)] penalty that would be calculated without applying the graduated penalty.

2. Voluntary Disclosure

Facilities that conduct an environmental audit or implement a compliance management system and promptly self-disclose any violations may be eligible for a significant reduction in the gravity-based penalty if they meet the nine criteria established in EPA's Audit Policy (Incentives for Self-Policing: Disclosure, Correction and Prevention of Violations: Final Policy Statement, April 11, 2000). A facility may also be eligible for penalty reductions if they meet the specific criteria outlined in the "Small Business Compliance Policy" (May 11, 2000). If a facility self-discloses violations that do not qualify under the Audit Policy or Small Business Compliance Policy, the Agency may consider a company's willingness to disclose as good faith (see Section IV.B.3.b.i. Good Faith Adjustments).

3. Adjusting the Proposed Civil Penalty in Settlement

Certain circumstances may justify adjustment of the proposed penalty. These circumstances may come to EPA's attention when a respondent files an answer to a civil complaint or during pre-filing settlement discussions under the *Consolidated Rules of Practice Governing Administrative Assessment of Civil Penalties*, 40 C.F.R. Part 22.

a. Factual Changes

EPA will recalculate the proposed penalty if the respondent can demonstrate that the size of business category, the gravity level, or the gravity adjustment criteria (Appendix B) used to derive the penalty is inaccurate. Adjustments to the proposed civil penalty may also be appropriate if the respondent can demonstrate an inability to pay the civil penalty (see Section IV.A.7. Ability to Continue in Business/Ability to Pay). Where additional facts indicate that the original penalty is not appropriate, EPA will calculate a new penalty consistent with the new facts. The burden is on the respondent to raise those factors which may justify the recalculation.

b. Negotiations Involving Only the Amount of the Penalty

In some cases the respondent may admit to all jurisdictional and factual allegations alleged in the complaint and may desire a settlement conference limited to the amount of the proposed penalty. The following sections describe adjustments that EPA may consider during settlement negotiations if the specific case meets the criteria set forth below.

i. Good Faith Adjustments

During the course of settlement negotiations, EPA may consider evidence of significant good faith efforts by the respondent to comply with FIFRA prior to the discovery of the violation(s) by EPA or a state as well as the respondent's good faith efforts to comply with FIFRA expeditiously after the discovery of the violation(s) by EPA or a state. In such instances, EPA may reduce the penalty by as much as 20 percent below the proposed penalty, if such a reduction would serve the public interest. A reduction for good faith efforts to comply is not mandated in any case. Such a reduction in penalty should only occur where there is an appropriate showing by respondent and finding by the Agency. Additionally, no reduction based on good faith efforts of the respondent should extend beyond a total of 20 percent of the proposed penalty without a showing of "special circumstances," as discussed below. No downward adjustment should be made if the Respondent fails to correct the violation(s) promptly after EPA or a state discovers the violation(s). Moreover, no downward adjustment should be made because respondent lacks knowledge concerning either applicable requirements or violations committed by respondent.

ii. Special Circumstances/Extraordinary Adjustments

Should EPA determine in a particular case that equity would not be served by adjusting the proposed penalty by only the allowable 20 percent adjustment for good faith, the FIFRA program manager may approve an adjustment to the proposed penalty for up to an additional 20 percent. In such cases, the case file must include substantive reasons why the extraordinary reduction of the civil penalty was appropriate, including: (1) setting forth the facts of the case; (2) why the penalty derived from the FIFRA civil penalty matrices and gravity adjustment was

inequitable; (3) how all other methods for adjusting or revising the proposed penalty would not adequately resolve the inequity; and (4) the manner in which the adjustment of the penalty effectuated the purposes of the Act. The FIFRA program manager's concurrence in the extraordinary reduction must be included in the case file.

iii. Supplemental Environmental Projects (SEPs)

To further EPA's goals to protect and enhance public health and the environment, certain environmentally beneficial projects, or Supplemental Environmental Projects (SEPs), may be included in the settlement. SEPs are environmentally beneficial projects which a respondent agrees to undertake in settlement of an environmental enforcement action, but which the respondent is not otherwise legally required to perform. In return, some percentage of the cost of the SEP is considered as a factor in establishing the final penalty to be paid by the respondent. EPA has broad discretion to settle cases with appropriate penalties. Evidence of a violator's commitment and ability to perform a SEP is a relevant factor for EPA to consider in establishing an appropriate settlement penalty. While SEPs may not be appropriate in settlement of all cases, they are an important part of EPA's enforcement program. Whether to include a SEP as part of a settlement of an enforcement action is within the sole discretion of EPA. EPA will ensure that the inclusion of a SEP in settlement is consistent with "EPA Supplemental Environmental Projects Policy," effective May 1, 1998, or as revised.

APPENDICES

Appendix A - FIFRA Violations and Gravity Levels

Appendix B - Gravity Adjustment Criteria

Appendix C - Summary of Tables

Appendix D - FIFRA Civil Penalty Calculation Worksheet

Appendix E – Enforcement Response Policy for FIFRA Section 7(c) – Pesticide Producing Establishment Reporting Requirements

Appendix F – FIFRA: Worker Protection Standard (WPS) Penalty Policy – Interim Final

Appendix G – Enforcement Response Policy for the FIFRA Good Laboratory Practices (GLP) Regulations

APPENDIX A

FIFRA VIOLATIONS AND GRAVITY LEVELS

FIFRA SECTION	CODE	VIOLATION	LEVEL
12(a)(1)(A)	1AA	Sold or distributed a pesticide NOT REGISTERED under section 3 or one whose registration was CANCELLED or SUSPENDED, except to the extent authorized by the administrator.	1
12(a)(1)(A)	1AB	Registrant, wholesaler, dealer, retailer, or any other distributor ADVERTISED, or otherwise "offered for sale" in any medium a pesticide that was NOT REGISTERED under section 3 or that was CANCELLED or SUSPENDED, other than in accordance with Agency policy.	2
12(a)(1)(B)	1BA	CLAIMS made for a pesticide as part of its sale or distribution differed substantially from those accepted in connection with registration	2
12(a)(1)(B)	1BB	Registrant, wholesaler, dealer, retailer, or the other distributor ADVERTISED, or otherwise "offered for sale" in any medium a registered pesticide product for an UNREGISTERED USE, other than in accordance with Agency policy.	2
12(a)(1)(C)	1CA	Sold or distributed a pesticide whose COMPOSITION DIFFERED from the composition represented in the registration	2
12(a)(1)(D)	1DA	Sold or distributed a pesticide that has not been COLORED or DISCOLORED pursuant to section 25(c)(5)	2
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(A)	1EA	Sold or distributed a pesticide or device which is MISBRANDED in that the labeling has a statement, design, or graphic representation that is false or misleading.	2[i]
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(B)	1EB	Sold or distributed a pesticide or device which is MISBRANDED in that the package or other container or wrapping does not conform to the standards established pursuant to section 25(c)(3) (e.g., not contained in child-resistant packaging or safety containers).	2[1]
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(C)	1EC	Sold or distributed a pesticide or device that is MISBRANDED in that it is an imitation of, or is offered for sale under the name of, another pesticide.	2[1]
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(D)	1ED	Sold or distributed a pesticide or device that is MISBRANDED in that the label did not bear the registration number assigned under section 7.	4
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(E)	1EE	Sold or distributed a pesticide or device that is MISBRANDED in that any words, statements, or other information required by the Act were not prominently placed on the label or labeling in such a way as to make it readable or understandable.	3
12(a)(1)(E) 12(a)(1)(F) 2(q)(1)(F)	1EF	Sold or distributed a pesticide or device that is MISBRANDED in that the label, or labeling accompanying it, did not contain directions for use necessary to make the product effective and to adequately protect health and the environment.	1
12(a)(1)(E)	1EG	Sold or distributed a pesticide or device that is MISBRANDED in	2[1]

FIFRA SECTION	CODE	VIOLATION	LEVEL
12(a)(1)(F) 2(q)(1)(G)		that the label did not contain a warning or caution statement adequate to protect health and the environment (precautionary statements)	
12(a)(1)(E) 2(q)(1)(H)	1EH	Sold or distributed a non-registered pesticide intended for export that is MISBRANDED in that the label did not have a prominently displayed "Not Registered for Use in the United States of America"	2[1]
12(a)(1)(E) 2(q)(2)(A)	1EI	Sold or distributed a pesticide that is MISBRANDED in that the label did not bear an ingredient statement on the immediate container which is presented or displayed under customary conditions of purchase.	3
12(a)(1)(E) 2(q)(2)(B)	1EJ	Sold or distributed a pesticide that is MISBRANDED in that the labeling does not contain a statement of the use classification under which the product was registered	2
12(a)(1)(E) 2(q)(2)(C)	1EK	Sold or distributed a pesticide that is MISBRANDED in that there is not a label affixed to the pesticide container, and to the outside wrapper of the retail package if the required information on the immediate container cannot be clearly read, a label bearing all of the following information: (i) the name and address of the producer, registrant, or person for whom produced (ii) the name brand, or trademark under which the pesticide is sold (iii) the net weight or measure of the contents; and (iv) when required by regulation, the registration number assigned to the pesticide.	 3 4 4 3
12(a)(1)(E) 2(q)(2)(D)	1EL	Sold or distributed a pesticide that is MISBRANDED in that the pesticide is sold in quantities highly toxic to man and the label failed to bear the skull and crossbones, and the word "poison," prominently in red on a contrasting background color, and a statement of practical treatment.	1
12(a)(1)(E) 2(c)(1)-(3)	1EM	Sold or distributed a pesticide that is ADULTERATED in that: (i) the strength or purity falls below the professed standard of quality expressed on the labeling; (ii) any substance has been substituted wholly or in part for the pesticide; or (iii) any valuable constituent of the pesticide has been wholly or in part abstracted.	2
12(a)(2)(A)	2AA	DETACHED, ALTERED, DEFACED, OR DESTROYED, in whole or in part, any LABELING required under the Act.	2
12(a)(2)(B)(i)	2BA	Refused to PREPARE, MAINTAIN, or SUBMIT any RECORDS required under sections 5, 7,[ii] 8, 11, or 19.	2
12(a)(2)(B)(ii)	2BB	Refused to SUBMIT any REPORTS required by or under sections 5, 6, 7,[2] 8, 11, or 19.	2
12(a)(2)(B)(ii)	2BC	A registrant refused to submit REPORTS under section 6(a)(2) regarding UNREASONABLE ADVERSE EFFECTS of their pesticide.	1
12(a)(2)(B)(iii)	2BD	Person refused to allow ENTRY, INSPECTION, COPYING OF RECORDS, or SAMPLING authorized by this Act.	2
12(a)(2)(C)	2CA	Person gave a GUARANTY or undertaking provided for in section	2

FIFRA SECTION	CODE	VIOLATION	LEVEL
		12(b) which was FALSE in any particular.	
12(a)(2)(D)	2DA	Person used their personal advantage or revealed to persons other than those authorized by the Act any INFORMATION acquired under the Act that was CONFIDENTIAL.	3
12(a)(2)(E)	2EA	Registrant, wholesaler, dealer, retailer, or other distributor ADVERTISED a RESTRICTED USE PESTICIDE without indicating that the product was restricted.	2
12(a)(2)(F)	2FA	Person DISTRIBUTED, SOLD, MADE AVALIABLE FOR USE, or USED a RESTRICTED USE PESTICIDE for a purpose other than in accordance with section 3(d) or regulations issued.	~~3~~ 2
12(a)(2)(F)	2FB	Person distributed, sold, or made available for use, or used, a RESTRICTED USE PESTICIDE without maintaining the RECORDS required by regulations (A Notice of Warning should be issued for first-time partial violations. Violations continuing subsequent to the issuance of a civil complaint are to result in a suspension- see "Denials, Suspensions, Modifications, or Revocations of Applicator Certifications" section of this ERP).	2
12(a)(2)(G)	2GA	Person USED a registered pesticide in a manner inconsistent with its labeling.	2
12(a)(2)(H)	2HA	Person USED a pesticide under an EXPERIMENTAL USE PERMIT contrary to the provisions of the permit.	2
12(a)(2)(I)	2IA	Person violated any order issued under section 13 (*i.e.*, STOP SALE, USE, OR REMOVAL ORDER, or SEIZURES.	1
12(a)(2)(J)	2JA	Person violated any SUSPENSION ORDER issued under section 6.	1
12(a)(2)(J)	2JB	Person violated any SUSPENSION ORDER issued under section 3(c)(2)(B) or 4.	2
12(a)(2)(K)	2KA	Person violated any CANCELLATION ORDER issued under the Act on grounds of UNREASONABLE ADVERSE EFFECTS.	1
12(a)(2)(K)	2KB	Person violated any CANCELLATION ORDER issued under the Act on grounds OTHER THAN UNREASONABLE ADVERSE EFFECTS.	2
12(a)(2)(K)	2KC	Person failed to submit a SECTION 6(g) NOTICE when required.	2
12(a)(2)(K)	2KD	Person submitted a NOTABLY LATE SECTION 6(g) NOTICE.	3
12(a)(2)(K)	2KE	Person submitted an INCOMPLETE or INCORRECT SECTION 6(g) NOTICE.	3
12(a)(2)(L) 7(a)[2]	2LA	PRODUCED a pesticide or active ingredient subject to the Act in an UNREGISTERED ESTABLISHMENT.	2
12(a)(2)(L) 7(c)(1)[2]	2LB	Producer FAILED TO SUBMIT, or submitted NOTABLY LATE, a REPORT to the administrator, under SECTION 7, which indicates the types and amounts of pesticides or active ingredients which they are currently producing, which they produced during the year, and which they sold or distributed during the past year.	2
12(a)(2)(L) 7(c)(1)[2]	2LC	Producer submitted a LATE REPORT to the administrator, under SECTION 7, which indicates the types and amounts of pesticides or active ingredients which they are currently producing, which they produced during the year, and which they sold or distributed during	4

FIFRA SECTION	CODE	VIOLATION	LEVEL
		the past year (civil complaint issued only if the producer does not respond to a Notice of Warning or there is a subsequent violation within three year timeframe from the first violation).	
12(a)(2)(L) 7(c)(1)[2]	2LD	Producer submitted an INCOMPLETE SECTION 7 REPORT with MINOR OMISSIONS of the required information (civil complaint issued only if the producer does not respond to a Notice of Warning or there is a subsequent violation within three year timeframe from the first violation).	3
12(a)(2)(L) 7(c)(1)	2LE	Producer submitted an INCOMPLETE or a FALSE SECTION 7 REPORT with MAJOR OMISSIONS or ERRORS of the required information.	2
12(a)(2)(L) 7(c)2	2LF	Upon request of the administrator for the purposes of the issuance of a section 13 Stop Sale Orders, a PRODUCER FAILED TO PROVIDE the names and addresses of any recipients of any pesticides produced in any of his registered establishments.	1
12(a)(2)(M)	2MA	Person KNOWINGLY FALSIFIED all or any part of an application for registration, application for an experiment use permit, any information submitted under section 7, any records required to be maintained by the Act, any reports filed under the Act, or any information marked as confidential and submitted to the administrator under any provision of the Act.	1
12(a)(2)(N)	2NA	A registrant, wholesaler, dealer, retailer, or other distributor FAILED TO FILE REPORTS (other than reports addressed in the section 7(c) ERP) required by the Act.	2
12(a)(2)(O)	2OA	Person ADDED A SUBSTANCE TO or TOOK any substance from a pesticide in a manner that may defeat the purpose of the Act.	2
12(a)(2)(P)	2PA	Person USED a pesticide in TESTS ON HUMAN BEINGS in violations of the conditions specified by the Act.	1
12(a)(2)(Q)[3]	2QA	Person FALSIFIED INFORMATION RELATING to the TESTING of any pesticide (or any of its ingredients, metabolites, or degradation products)that the person knows will be furnished to the administrator, or will become a part of any records required to be maintained by the Act	1
12(a)(2)(Q)[3]	2QB	Person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a HIGH LEVEL GLP violation.	2
12(a)(2)(Q)[3]	2QC	Person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a MID LEVEL GLP violation.	3
12(a)(2)(Q)[3]	2QD	14(a)(1) person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a LOW LEVEL GLP violation.	4
12(a)(2)(Q)[3]	2QE	14(a)(2) person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a LOW LEVEL GLP violation.	3
12(a)(2)(R)[3]	2RA	Person submitted DATA KNOWN TO BE FALSE in support of registration.	1

FIFRA SECTION	CODE	VIOLATION	LEVEL
12(a)(2)(S)[4]	2SA	Person sold, distributed, or used an UNREGISTERED pesticide in violation of a REGULATION ISSUED UNDER SECTION 3(a).	
12(a)(2)(S)[4]	2SB	Person violated any REGULATION ISSUED UNDER SECTION 19.	

[1] If a label has two or more Level 2 misbranding violations, the appropriate gravity level is increased to Level 1.
[2] Section 7(c)(1) violations are covered in the Enforcement Response Policy for FIFRA Section 7(c), Pesticide producing Establishment Reporting requirement dated June 2007.
[3] Violations regarding laboratory practice are covered in the FIFRA Good Laboratory Practice (GLP) Regulations dated September 30, 1991.
[4] Gravity levels for these violations will be assigned in subsequent ERPs.

APPENDIX B

GRAVITY ADJUSTMENT CRITERIA[1]

VIOLATION GRAVITY OF HARM	VALUE	CIRCUMSTANCES
Pesticide	3	Toxicity - Category I pesticides, signal word "Danger," restricted use pesticides (RUPs), pesticides with flammable or explosive characteristics (*i.e.*, signal words "Extremely Flammable" or "Flammable"), or pesticides that are associated with chronic health effects (mutagenicity, oncogenicity, teratogenicity, etc.) or pesticide is unregistered and the ingredients or labeling indicate Category I toxicity.
	2	Toxicity - Category II, signal word "Warning" or pesticide unregistered and unknown, but not expected to meet Category I toxicity criteria.
	1	Toxicity – Category III or IV, signal word "Caution" or pesticide unregistered and ingredients lower or minimum risk category.
Harm to Human Health	5	Actual serious or widespread[1] harm to human health.
	3	Unknown or potential serious or widespread harm to human health
	1	Minor[2] potential or actual harm to human health.
	0	Negligible[3] harm to human health anticipated.
Environmental Harm	5	Actual serious or widespread[1] harm to the environment (*e.g.*, crops, water, livestock, wildlife, wilderness, or other sensitive natural areas).
	3	Unknown or potential serious or widespread[1] harm to the environment health
	1	Minor[2] potential or actual harm to the environment.
	0	Negligible[3] harm to the environment anticipated.
Compliance History[4]	4	Violator with more than one prior violation of FIFRA.
	2	Violator with one prior violation of FIFRA.
	0	No prior FIFRA violations.
Culpability[5]	4	Knowing or willful violation of the statute.[6] Knowledge of the general hazardousness of the activity.
	2	Culpability unknown or violation resulting from negligence.
	1	Violation resulted from negligence. Violator instituted steps to correct the violation immediately after discovery of the violation.
	0	Violation was neither knowing nor willful and did not result from negligence. Violator instituted steps to correct the violation immediately after discovery of the violation.

APPENDIX B NOTES

[1] For the purposes of this ERP, serious or widespread harm refers to actual or potential harm which does not meet the parameters of minor harm or negligible harm, as described below.

[2] For the purposes of this ERP, minor harm refers to actual or potential harm which is, or would be of short duration, no lasting effects or permanent damage, effects are easily reversible, and harm does not, or would not result in significant monetary loss.

[3] For the purposes of this ERP, negligible harm refers to no actual or potential harm or actual or potential harm which is insignificant or unnoticeable and has no lasting effects or permanent damage or monetary loss.

[4] The following considerations apply when evaluating compliance history for the purposes of Appendix B:

(a) In order to constitute a prior violation, the prior violation must have resulted in: (1) a final order, either as a result of an uncontested complaint, or as a result of a contested complaint which is finally resolved against the violator; (2) a consent order, resolving a contested or uncontested complaint by the execution of a consent agreement; (3) the payment of a civil penalty by the alleged violator in response to the complaint, whether or not the violator admits to the allegations of the complaint; or (4) conviction under the FIFRA's criminal provisions.

A notice of warning (NOW) will not be considered a prior violation for the purposes of the gravity adjustment criteria, since no opportunity has been given to contest the notice. Additionally, a stop sale, use, or removal order (SSURO) issued under FIFRA section 13 will not be considered as compliance history.

(b) To be considered a compliance history for the purposes of Appendix B, the violation must have occurred within five years of the present violation. This five-year period begins on the date of a final order, consent order, or payment of a civil penalty.

(c) Generally, companies with multiple establishments are considered as one when determining compliance history. If one establishment of a company commits a FIFRA violation, it counts as history when another establishment of the same company, anywhere in the country, commits another FIFRA violation

(d) An enforcement action or citation issued by a state lead agency will count as a prior violation if all the above considerations are met.

[5] EPA enforcement officials are not required to determine culpability at the time the complaint is issued (especially if this information is not readily available). EPA enforcement officials may instead assign a weighting factor of 2 (culpability unknown), at the time of the issuance of the complaint. Culpability adjustments may be reconsidered during settlement negotiations.

[6] The Agency may also consider criminal proceedings for "knowing and willful" violations. See the "Criminal Proceedings" section of this ERP.

APPENDIX C
SUMMARY OF TABLES

TABLE 1

SIZE OF BUSINESS CATEGORIES

Section 14(a)(1) violators:
I - over $10,000,000 a year
II - $1,000,000 - $10,000,000
III - under $1,000,000

Section 14(a)(2) violators:
I - over $1,000,000 a year
II - $300,000 - $1,000,000
III - under $300,000

TABLE 2

FIFRA CIVIL PENALTY MATRICES

Civil Penalty Matrix for FIFRA § 14(a)(1)

	SIZE OF BUSINESS		
LEVEL OF VIOLATION	**I – over $10,000,000**	**II - $1,000,000 - $10,000,000**	**III – under $1,000,000**
Level 1	$7,500	7,150	7,150
Level 2	7,150	5,670	4,250
Level 3	5,670	4,250	2,830
Level 4	4,250	2,830	1,420

Civil Penalty Matrix for FIFRA § 14(a)(2) *

	SIZE OF BUSINESS		
LEVEL OF VIOLATION	**I – over $1,000,000**	**II - $300,000 - $1,000,000**	**III – under $300,000**
Level 1	$1,100	1,100	1,100
Level 2	1,100	1,030	770
Level 3 & 4	1,030	770	650

* This 14(a)(2) matrix is only for use in determining civil penalties issued subsequent to a notice of warning or following a citation for a prior violation, or in the case of a "for hire" applicator using a registered general use pesticide, subsequent to the issuance of a prior civil penalty.

TABLE 3

GRAVITY ADJUSTMENT CRITERIA

Total Gravity Value from Appendix B	**Enforcement Remedy**
3 or below	No action or Notice of Warning (60% reduction of matrix value recommended where multiple count violations exist)
4	Reduce matrix value 50%
5	Reduce matrix value 40%
6	Reduce matrix value 30%
7	Reduce matrix value 20%
8	Reduce matrix value 10%
9 to 11	Assess matrix value
12	Increase matrix value 10% **
13	Increase matrix value 20% **
14	Increase matrix value 30% **
15	Increase matrix value 40% **
16	Increase matrix value 50% **
17 or above	Increase matrix value 60% **

** Matrix value can only be increased to the statutory maximum.

APPENDIX D
FIFRA CIVIL PENALTY CALCULATION WORKSHEET

Respondent: **Docket No.:**	**Brief Description of Violation**
APPENDIX A 1. Violation	
2. FTTS Code & Violation Level	
TABLE 1 3. Violator Category & Size of Business Category	
APPENDIX A 4. Gravity of the Violation	
TABLE 2 5. Base Penalty	
APPENDIX B 6. Gravity Adjustments a. Pesticide Toxicity	
b. Harm to Human Health	
c. Environmental Harm	
d. Compliance History	
e. Culpability	
f. Total Gravity Adjustment (Add 6a - 6e)	
TABLE 3 7. Percent & Dollar Adjustment	
8. Economic Benefit	
TABLE 4 9. Graduated Penalty	
10. Final Penalty	

_____ _____

Case Development Officer Date

Example
FIFRA CIVIL PENALTY CALCULATION WORKSHEET

Respondent: **Docket No.:**	**Brief Description of Violation**
APPENDIX A 1. Violation	§12(a)(1)(C)
2. FTTS Code & Violation Level	1CA / 2
TABLE 1 3. Violator Category & Size of Business Category	§14(a)(1) / Category I
APPENDIX A 4. Gravity of the Violation	2
TABLE 2 5. Base Penalty	$7,150
APPENDIX B 6. Gravity Adjustments a. Pesticide Toxicity	1
b. Harm to Human Health	3
c. Environmental Harm	3
d. Compliance History	0
e. Culpability	2
f. Total Gravity Adjustment (Add 6a - 6e)	9
TABLE 3 7. Percent & Dollar Adjustment	Assess Matrix Value
8. Economic Benefit	
TABLE 4 9. Graduated Penalty	Not applied
10. Final Penalty	**$7,150 x 10 Violations = $71,500**

Case Development Officer

Date

Office of Enforcement and Compliance Assurance

INSPECTION MANUAL

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Inspection Manual

Number: OECA-MANL-2019-001-R0
August 1, 2019
U.S. Environmental Protection Agency



U.S. Environmental Protection Agency Office of Enforcement & Compliance Assurance Controlled Document	
STANDARD OPERATING PROCEDURE	
Title: FIFRA Inspection Manual	
Effective Date: August 1, 2019	**Number: OECA-MANL-2019-001-R0**
Author	
Name: Helene Ambrosino Title: Staff Attorney Office: OC/MAMPD/PWTB Signature: Helene Ambrosino	Date: 7/11/19
Approvals	
Name: Susan Laessig Title: Acting Branch Chief Office: OC/MAMPD/PWTB Signature: Susan A. Laessig	Date: 7/11/19
Name: Rick Duffy Title: Deputy Director Office: OC/MAMPD Signature: RDuffy	Date: 7/11/19
Name: Martha Segall Title: Acting Director Office: OC/MAMPD Signature: Martha Segall	Date: 7/11/19
Name: David Meredith Title: Quality Office: OC Signature: David Meredith	Date: 7/11/19

United States
Environmental Protection Agency
Revised 2019

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Inspection Manual



U.S. Environmental Protection Agency
Office of Enforcement and Compliance Assurance
Office of Compliance
1200 Pennsylvania Avenue, NW
Washington DC, 20460

DISCLAIMER

This Inspection Manual is an inspection support tool provided by the U.S. Environmental Protection Agency (EPA), for use by EPA regions, states and tribes conducting federal inspections under the Federal Insecticide, Fungicide, and Rodenticide Act. This Inspection Manual is not a regulation and, therefore, does not add, eliminate or change any existing regulatory requirements. The statements in this document are intended solely as guidance. This document is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States. EPA, state and tribal officials may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on analysis of specific-site circumstances. This guidance may be revised without public notice to reflect changes in EPA's policy.

FOREWORD

The purpose of this Manual is to assist inspectors who conduct inspections pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This Manual applies to all FIFRA inspections.

To help us update the Manual so that it remains a viable working tool, readers are encouraged to offer suggestions, amendments and constructive criticism generated by their field experience and use of the Manual. Comments should be forwarded to Helene Ambrosino at EPA Headquarters ambrosino.helene@epa.gov, 202-564-2627.

REVISION HISTORY

February 2014 — Chapter 6 was revised at the request of EPA's Office of Civil Enforcement. The revision sets forth a protocol on obtaining records documenting the distribution and sale of sampled product.

March 2014 — Changed contact for comments on the Manual.

August 2019

Chapter	Revision
General	A comprehensive review and update of the 2013 FIFRA Inspection Manual to reflect clarifications and new policy, guidance, etc,, as appropriate.
1	Updated CBI section. Updated Exhibit 1-1. Deleted Exhibit 1-2. Added reference Interim Policy on Inspection Streamlining and Standardization.
2	Deleted Exhibit 2-1 and referenced EPA health and safety courses in the chapter. Added reference to 2016 Biosecurity Guidance.
3	Added new guidance and policies. Added language on new SOPs for field activities.
4	Updated the Interagency Referral section.
5	Updated language concerning Notice of Inspection and Consent to Entry.
6	Updated Payment for Samples section. Updated language concerning the sampling of Liquid Material. Updated language in Samples Showing Shipment to delete reference to collecting one year's worth of records.
8	Deleted reference to obsolete Form 3540-20.
9	Added a reference to the National List of Active Establishments available online. Added additional bullets to section on pre-inspection preparation. Added checklists for container/containment inspections.
12	Updated language concerning imports to include references to ACE and Foreign Trade Zones.
16	Added language on the difference between a "statement" and an "affidavit". Added reference to Interim Policy on Inspection Streamlining and Standardization.

FIFRA INSPECTION MANUAL

TABLE OF CONTENTS

Chapter 1: General Information

Chapter 2: Health and Safety

Chapter 3: Pesticide Law, Policy and Compliance Strategies

Chapter 4: Federal, State and Tribal Cooperation

Chapter 5: Gaining Entry

Chapter 6: Pesticide Product Sampling

Chapter 7: Residue and Environmental Sampling

Chapter 8: Use Inspections

Chapter 9: Establishment Inspections

Chapter 10: Experimental Use Permit Inspections

Chapter 11: Restricted Use Pesticides: Dealer and Applicator Records Inspections

Chapter 12: Pesticide/Device Import and Export Inspections

Chapter 13: Cancellation and Suspension

Chapter 14: Stop Sale, Use, or Removal Orders

Chapter 15: Recalls

Chapter 16: Inspection Reports and Supporting Documentation

Chapter 17: Enforcement

CHAPTER ONE
GENERAL INFORMATION

CONTENTS

Standards of Professional Conduct 2
Professional Attitude 3
Attire and Personal Protective Equipment 3
Relationships with Industry and the Public 3
Gifts, Favors and Meals 3
Knowledge Required of a FIFRA Inspector 4
Small Businesses 5
Disclosure of Official Information 5
- Requests for Information by Industry or the Public 5
- Confidential Business Information 5
- Procedures for CBI Acquired by an EPA Inspector During an Inspection 6
- Procedures for CBI Requested by a State or Tribal Inspector 6

Exhibit 1-1: EPA Federal Forms used for FIFRA 8
- FIFRA Inspection Forms 8
- Other FIFRA Forms 8

GENERAL INFORMATION

This manual provides guidance to inspectors conducting pesticide inspections under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). It includes recommended procedures and forms for federal inspections.

Inspections are conducted in five phases: (1) inspection preparation; (2) entry and opening conference; (3) observations and evidence collection; (4) receipt for samples/statement(s) and closing conference; and (5) inspection reporting. Conducting all inspections in this manner will ensure that the inspector fulfills the statutory requirements for conducting inspections authorized under Sections 8 and 9 of FIFRA. EPA has developed forms for use during inspections that will assist the inspector in completing all phases. For a complete listing of the forms, see Exhibit 1-1.

STANDARDS OF PROFESSIONAL CONDUCT

The following standards of ethics must be observed at all times. The inspector shall:

- Conduct investigations within the framework of the United States Constitution and with due consideration for individual rights, regardless of race, sex, creed or national origin.
- Uphold the Constitution, laws and regulations of the United States and all governments therein and never be a party to their evasion.
- Never use any information obtained confidentially in the performance of governmental duties as a means of making private profit.
- Never commit any act (or failure to act) in a manner that might be construed as being motivated by personal or private gain (conflict of interest).
- Never discriminate by dispensing special favors or privileges to anyone, whether for remuneration or not; and never accept, for his/her or their families, favors or benefits under any circumstances.
- Develop and report facts of an investigation completely, objectively and accurately.
- Make no promises of any kind; government employees (inspectors) cannot bind government enforcement.
- Continually attempt to improve professional knowledge and technical skill in the investigative field.

PROFESSIONAL ATTITUDE

Because the inspector is often the initial or only contact between the Agency and industry or the public, he/she must be tactful, courteous and diplomatic, while establishing an atmosphere of cooperation through a firm but responsive attitude.

ATTIRE AND PERSONAL PROTECTIVE EQUIPMENT

Good public relations and practical common sense require appropriate dress for inspection activities. Protective clothing is required for many inspections. Inspectors must wear any safety equipment that may be customary in the establishment being inspected. Chapter 2 provides additional information on personal protective safety equipment.

RELATIONSHIPS WITH INDUSTRY AND THE PUBLIC

It is important to establish good working relationships with industry, the public and consumers. The inspector must introduce himself/herself by name, title and organization, present his/her credentials and explain the purpose of the visit. The inspector must not speak of any product manufacturer or person in a derogatory manner. All information acquired in the course of an inspector's duties is to be used for official purposes only.

There may be times when an inspector is requested to provide advice that amounts to compliance assistance. See the "National Policy on the Role of the EPA Inspector in Providing Compliance Assistance during Inspection."

If an inspector is approached by a member of the public, including the media, during an inspection, the inspector should respectfully refer any inquiries concerning the inspection to the EPA (or appropriate state/tribal) press office. The inspector must not divulge any information about the inspection. Where the media representative is persistent, it may be necessary to stop the inspection temporarily to allow time to consult with the EPA (or appropriate state/tribal) press office.

GIFTS, FAVORS AND MEALS

An inspector shall not accept anything of value from industry or the public for, or because of, any official act he/she has performed or will perform. However, an inspector may accept refreshments of nominal value in the ordinary course of a luncheon or dinner meeting or other meetings or on inspection tours when it is not proper or feasible for the inspector to pay. For more information on ethics standards, visit the U.S. Office of Government Ethics.

KNOWLEDGE REQUIRED OF A FIFRA INSPECTOR

A FIFRA Inspector must have knowledge of FIFRA and its implementing regulations (at 40 C.F.R. Parts 150-189), as well as the other requirements set forth in EPA Orders 1440.2 and 3500.1 including all Health and Safety Requirements (see Chapter 2).

A good inspector must have certain communication and intuitive skills in order to complete a thorough investigation. The inspector must know how to:

- Substantiate all statements of witnesses with facts or items of evidence.
- Collect and document evidence to support a successful civil action, criminal prosecution or seizure.
- Accurately and clearly write an inspection report, containing all information, data and other records, such as photos, gathered during the inspection.
- Obtain respect, inspire confidence and maintain the good will of the public, industry and consumers during interviews.
- Conduct sampling procedures in a safe and professional manner, preserving the chain of custody.
- Use good interview techniques and detect discrepancies or lack of good faith during interviews.
- Be accurate, thorough, unbiased and fair while conducting an investigation/inspection and preparing the inspection report.
- Testify in court.

In addition, an inspector should have generalized knowledge of the following federal laws and regulations that could be relevant to an inspection in that the facility being inspected may be subject to additional regulations. Links are included where available on-line:

- Clean Air Act (CAA)
- Federal Water Pollution Control Act (FWPCA)/ Clean Water Act (CWA)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Superfund Amendments and Reauthorization Act (SARA)
- Endangered Species Act (ESA)
- Emergency Planning and Community Right-To-Know Act (EPCRA)
- Federal Food, Drug, and Cosmetic Act (FFDCA)
- Hazardous Materials Transportation Act (HMTA)
- Occupational Safety and Health Act (OSHA)
- Resource Conservation and Recovery Act (RCRA)
- Safe Drinking Water Act (SDWA)
- Toxic Substances Control Act (TSCA)
- Appropriate state pesticide and environmental legislation
- Department of Transportation (DOT) Regulations

- Department of Homeland Security (DHS) – Customs and Border Protection Regulations at 19 C.F.R.; in particular sections 12.110 – 12.117
- Federal Facility Compliance Act (FFCA)

SMALL BUSINESSES

EPA provides a variety of resources to help small businesses understand and comply with federal and state law, in part, due to the Small Business Regulatory Enforcement Fairness Act (SBREFA). The EPA Small Business Resources Information Sheet is required to be given out during every inspection. The flyer provides useful information on resources for small business that may be faced with environmental compliance issues.

DISCLOSURE OF OFFICIAL INFORMATION

REQUESTS FOR INFORMATION BY INDUSTRY OR THE PUBLIC

The Freedom of Information Act (FOIA) governs the disclosure of information to industry and the public. Information about FOIA is available at http://www.epa.gov/foia/.

Federal inspectors as well as state or tribal inspectors performing federal inspections shall not release under FOIA or similar state law, any notes, documents, reports, etc. obtained or prepared in connection with a FIFRA inspection until such time as authorized by EPA. Should the state or tribe receive a FOIA or similar request for documentation relative to an open or ongoing FIFRA inspection, the state or tribe shall contact the EPA regional FIFRA program office or headquarters FIFRA Enforcement Office. EPA inspectors should refer to the "Interim Policy on Inspection Report Timeliness and Standardization", issued by OECA on June 29, 2018 or any subsequent final policy.

CONFIDENTIAL BUSINESS INFORMATION

Sections 10 and 12(a)(2)(D) of FIFRA address the protection of trade secrets and confidential business information (CBI). Only persons authorized by EPA are allowed access to CBI. See "FIFRA Information Security Manual". Information received that is marked "trade secret" or "confidential" must not be copied unless authorized in writing by EPA.

The written authorization to make copies must contain the following information:

1. The name of the recipient of the copy.
2. The intended purpose for which the copy is to be used.
3. The manner in which the copy is to be disposed of after use.

When a member of the public, or a representative from a state, local, tribal or federal agency requests access to any information considered confidential, the person handling the request

must comply with the procedures set forth in Subpart B of 40 C.F.R Part 2. All such requests must be referred to the appropriate EPA regional office.

State and tribal inspectors conducting inspections using federal credentials to conduct FIFRA section 8 and 9 inspections **are not authorized** to obtain or access CBI on behalf of EPA unless the claim of CBI has been waived. Additionally, where state or tribal inspectors are conducting an inspection under their own state or tribal authority, they may have CBI authority under state or tribal law.

Where a state or tribal inspector is conducting an inspection on behalf of EPA using federal credentials and records claimed as CBI are necessary to complete the inspection, the inspector must use the procedures described below. Check with your EPA regional office for the name of the current Document Control Officer (DCO).

PROCEDURES FOR CBI ACQUIRED BY AN EPA INSPECTOR DURING AN INSPECTION

During an opening conference, the inspector should raise the facilities right to make a claim of CBI. The following procedures must be adhered to when an EPA inspector receives FIFRA CBI:

1. The information received shall be marked as "FIFRA CBI" or the red FIFRA CBI cover sheet shall be attached to the information.
2. The CBI information shall be placed in an envelope, sealed and marked, "CBI—To Be Opened ONLY by Addressee" and the name of the Regional DCO. This envelope is then to be placed into another envelope which is normally addressed and sealed, with no indication that it contains CBI.
3. The envelope shall be given to the Regional DCO to be properly logged in as CBI.
4. CBI must be maintained only in a locked filing cabinet or safe.

PROCEDURES FOR CBI REQUESTED BY A STATE OR TRIBAL INSPECTOR

During an opening conference, the inspector should raise the facilities right to make a claim of CBI. The following procedures apply to state/tribal inspectors using federal credentials and federal authority:

1. The inspector shall request that the establishment place any information claimed to be CBI in a double sealed envelope.
2. The inspector shall list the requested information claimed to be CBI on the "Receipt for Samples" and/or "Statement Form".
3. The inspector shall provide the owner/operator with a correct address for the EPA Regional DCO to submit the CBI to EPA or, alternatively, the inspector may accept the double wrapped package containing CBI and deliver it unopened to EPA.

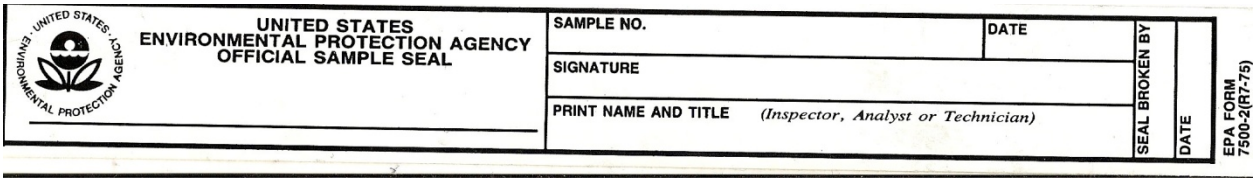
4. The inspector shall clearly document the list of requested information claimed to be CBI to be sent to the EPA DCO in the inspection report.
5. The inspector shall send the inspection report, noting the CBI requested on the "Receipt for Samples" and/or "Statement Form" and in the inspection report, to the EPA Regional Office or Headquarters, as appropriate.

EXHIBIT 1-1: EPA FEDERAL FORMS USED FOR FIFRA

FIFRA INSPECTION FORMS

The FIFRA inspection forms listed below are to be used during all inspections conducted using federal credentials. A region can supply the forms to regional staff, state lead agencies or tribal pesticide programs for use during an inspection conducted under federal authority and federal credentials. The forms cannot be changed or modified. Forms:

- 3540-2 Notice of Inspection
- 3540-3 Receipt for Samples
- 3540-4 Sample Jacket Cover Page
- 3540-13 Copy of Invoice/Shipping Records
- 3540-17 History of Sample (PDF) (516K, 1 pp)
- 3540-25 Notice of Inspection - Use/Misuse (Interactive PDF) (515K, 1 pp)
- 3540-26 Receipt for Samples - Use/Misuse (Interactive PDF) (515K, 1 pp)
- 3540-27 Stop Sale, Use, Removal Notice (Interactive PDF) (442K, 1 pp)
- 3540-41 Chain of Custody Form (PDF) (307K, 2 pp)
- 3540-42 Statement (Interactive PDF) (512K, 2 pp)
- 3540-43 FIFRA Photo Log
- 7500-2 Official Sample Seal


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
OFFICIAL SAMPLE SEAL

SAMPLE NO. | DATE

SIGNATURE

PRINT NAME AND TITLE (Inspector, Analyst or Technician)

SEAL BROKEN BY | DATE

EPA FORM 7500-2(R7-75)

FIGURE 1 - EPA OFFICIAL SAMPLE SEAL

OTHER FIFRA FORMS

- 3540-1 Notice of Arrival of Pesticides and Devices
- 3540-8 Application for Registering a Pesticide, Device or Active Ingredient Producing Establishment
- 3540-16 Pesticide Report for Pesticide-Producing and Device-Producing Establishments

CHAPTER TWO
HEALTH AND SAFETY

CONTENTS

Introduction....3
Personal Protective Equipment....3
Eye Protection....3
Foot Protection....4
Hand Protection....4
Ear Protection....5
Nasal, Mouth and Respiratory Protection....5
Head Protection....6
Back Protection....6
Clothing Protection....6
General Safety Precautions....7
Awareness....7
Man-Lifts and Cage-Type Elevators....8
Cage-Type Elevators....9
Man-lifts....9
Ladder Safety....9
Lifting Safety....10
Machine and Equipment Safety....10
Safety Signs....10
Electrical Safety....10
Confined Spaces....10
Safety While Sampling....11
Sampling Near Trucks and Trailers....12
Sampling Rail Cars....12
Boxcars....13
Hopper Cars....13

Sampling Bins and Tanks 14
Sampling Bagged or Packed Products 15
Sampling Bulk Bagged Products (Large Volume Bags) 15
Hazards and Hazardous Materials 15
Exposure to Hazardous Materials 17
Hazards 17
Entry and Exit 18
Inspector Responsibilities 18
Environmental Biological Hazards 18
Be Aware of Pathogen Hazards During an Inspection 18
Protecting Against Environmental Pathogens 19
Common Pathogens 20
Travel Safety 23
Vehicle Safety 23
Personal Safety 24
Lodging Safety 24

HEALTH AND SAFETY

INTRODUCTION

Manufacturing plants, blenders, processors, elevators, mills and warehouses can be hazardous work environments. Inspection of these places will, at times, include potentially hazardous situations. Personal health and safety must be a top priority for every inspector. To ensure maximum protection under any and all conditions:

- Prepare and plan for health and safety.
- Always bring and use safety equipment.
- Be aware of potential dangers posed at each type of establishment.
- Exercise care and use common sense at all times.
- Prevent accidents by specifically requesting and conforming to known safety practices. If there are questions about the safe way to do a job, ask a supervisor for help and instruction.
- Contact regional Safety, Health and Environmental Management Program Manager for pertinent health and safety information and to determine the eligibility and need for medical monitoring.

Note that EPA's Office of Compliance offers Health and Safety courses for inspectors that conduct field activities and are required to receive and maintain federal inspector credentials.

PERSONAL PROTECTIVE EQUIPMENT

FIFRA inspections take place in locations that may pose health and safety dangers to inspectors. Additionally, industrial solvents, pesticides, or fertilizers can corrode or destroy equipment, clothing and footwear. Therefore, it is critical to use Personal Protective Equipment (PPE) during FIFRA inspections. The following list of PPE is provided. Note that all PPE require regular cleaning, visual checks and maintenance.

EYE PROTECTION

Types of eye protection include:

- **Goggles**—Goggles form a tight seal around the eye area and provide an impervious barrier against objects getting into the eyes. They often may be uncomfortable and hard

to see through because of condensation. Goggles may be directly vented, indirectly vented or non-vented. Directly vented goggles may be used for particle deflection. They will not, however, be impervious to liquids. Indirectly vented goggles will afford protection from particles as well as most liquid spatters. Non-vented goggles should be used when dealing with anhydrous ammonia.

- **Face shield**—Face shields form a plane of protection in front of the eyes. The eyes, nose, and mouth can be protected from direct (perpendicular to the shield) exposure. Objects or substances coming from other directions, however, may get into the face or eyes. When not in use, the face shield may be flipped out of the way to wipe the face. A shield may also be easily used over prescription glasses. A face shield affords only secondary protection and must be used with either goggles or safety glasses.
- **Safety glasses**—Safety glasses are available in either clear lenses or prescription lenses. Like the shield, they do not afford protection from non-direct exposure. Side guards are available to protect from non-direct exposure and must be used to make them more effective. If glare may be a problem, tinting may be added.

FOOT PROTECTION

Types of foot protection include:

- **Footwear (shoes or work boots)**—Footwear should be comfortable to wear, fit properly and provide proper support. Secondly, it must have a steel toe or protective support in case objects are dropped on the foot. The sole and heel of the footwear must be appropriate for the working environment. Do not wear slick-soled shoes or sneakers. Use proper protective mechanisms to prevent your feet from being exposed to pesticides or caustic chemicals. Workers have become seriously ill from exposure through shoes or boots due to the footwear material soaking up the pesticide and exposing the person through skin contact. A good practice is to “waterproof” footwear; this function should be performed regularly.
- **Rubber or neoprene boots or galoshes**—Ordinary work boots or shoes are not suitable when handling pesticides. Rubber boots or neoprene boots must be worn. Rubber boots provide a protective barrier against water and some solvents. They also may be easily cleaned. Neoprene boots will afford protection from various chemicals and solvents. Either “gum” boots, pull-over boots, or buckle boots may be used.
- **Tyvek booties**—Tyvek booties can be worn over shoes/boots and add a large degree of protection from absorption of chemicals into shoes, boots, and the body.

HAND PROTECTION

Hand protection comes in many forms. The class and material of gloves used must be taken into account when selecting the proper type for use. Certain gloves may have long shanks and afford protection for the wrist or lower arm. Be aware that cuffs present a hazard by allowing material to collect in the cuff or getting caught in machinery. When necessary, inspectors must use the following to protect their hands:

- **Work gloves (cotton or jersey)**—Cotton or jersey work gloves will provide warmth in the winter and some protection from dirt and blisters. Be careful not to use cotton or cloth gloves when working with pesticides, chemicals, or solvents. Cloth gloves will act as a wick and absorb these products, allowing continued contact with the skin.
- **Disposable latex gloves**—Disposable latex gloves are easy to use and afford protection from some fertilizers, seed treatments, dirt, grease, non-corrosive materials or liquids. They are easy to use and readily disposable. However, some people may be allergic to latex. If a rash occurs, seek proper medical attention. A disadvantage of latex gloves is that they do not afford protection against corrosive materials or certain chemicals. When using latex gloves, determine for what products the gloves are rated.
- **Heavy rubber gloves**—Heavy rubber gloves afford the best protection when working around pesticides or other similar products. These gloves are easily rinsed or cleaned when liquids are spilled on them.

EAR PROTECTION

Types of ear protection include:

- **Disposable foam plugs**—Disposable foam plugs are inexpensive, easily stored and used; but they may be uncomfortable to wear. Make sure the plugs are rated with the proper protection for the environment you will be working in.
- **Padded hearing protectors**—Padded hearing protectors are the typical "headphone" type protectors. They afford noise protection as well as a cover for the ear. Usually they are rated higher than typical plugs and prevent compacting in the ear canal.

NASAL, MOUTH AND RESPIRATORY PROTECTION

NOTE: THE USE OF RESPIRATORS AND SELF CONTAINED BREATHING APPARATUSES (SCBA'S) REQUIRES "FIT TESTING" AND A YEARLY CERTIFICATION OF THE "FIT TEST." IN ADDITION, MEDICAL MONITORING IS REQUIRED. ALL CERTIFICATION RECORDS SHOULD BE RETAINED BY THE INSPECTOR'S SUPERVISOR.

Respiratory protection equipment includes:

- **Disposable dust masks**—Disposable dust masks are easily worn and afford little or no protection from pesticides. However, they may be used for general dust and limited

airborne particulates. Dust masks only prevent particles from passing through, and offer little or no protection against caustic or dangerous fumes, pesticides, etc.

- **Respirator**—Respirators usually contain various filters that can be interchanged depending upon the hazards of the working environment. Filters are rated for particular substances. Be aware of the respirator's rating and the protection it affords. Likewise, be aware of the respirator's limitations. Respirators must never be used in oxygen-deficient environments.
    - NOTE: Facial hair may prevent a tight seal.
    - Test according to the manufacturer's directions to ensure an air-tight seal.
    - Achieving an air-tight seal may present a greater problem for women than for men because many respirators are sized to fit a man's face. Ensure that a tight fit can be achieved prior to leaving the office.
- **Air packs**—Self-contained breathing apparatuses (SCBA) contain a mask, oxygen tank, and regulator. Before using SCBA, inspectors must have attended the 40-hour Hazard Materials Training course and obtained a physician's approval to wear it. It is extremely important that two SCBA-trained people be on hand when entering oxygen deficient environments. *ALL CERTIFICATION RECORDS SHOULD BE RETAINED BY THE INSPECTOR'S SUPERVISOR.*

HEAD PROTECTION

Proper head protection is recommended during most inspections. Steel or molded hats protect the head and skull from falling objects or head height obstacles.

BACK PROTECTION

When lifting heavy objects, use a proper back support or lift belt.

CLOTHING PROTECTION

The inspector should wear clothing protection to prevent-cross contamination of sites and/or samples as well as providing protection to the inspector and preventing contamination of the inspector's home or office. Inspectors should use the following:

- **Cloth coveralls**—Protective outerwear is available to be worn over your normal clothing. Lightweight coveralls can be used during the summer months while insulated coveralls can be used in the winter. These coveralls will keep clothing from receiving stains while in dirty work environments.

- **Tyvek coveralls**—Tyvek is an extremely lightweight, disposable paper-like substance that is extremely hard to tear. Tyvek is the preferred material because, unlike cloth, it does not absorb and, if contaminated, can be discarded. Tyvek is chemical-resistant.

GENERAL SAFETY PRECAUTIONS

Generally, while conducting inspections:

- Inspectors must inform facility personnel where they are going to be within the facility. Inspectors should specifically request information on possible dangers or areas to avoid during the inspection. Follow all safety requirements established by facility. For example, vehicular traffic within the plant grounds may not follow normal movement patterns nor obey usual traffic rules. Also, the nature and size of equipment used may make it difficult for the driver to see persons working nearby.
- Wearing jewelry, ties, loose flowing clothing, having long flowing hair, etc. can pose a safety hazard to the inspector around equipment or machinery.
- Prior to entering the plant or facility, inquire about the firm's safety polices. Many firms require visitors to wear a hard hat and/or safety glasses. Hardhats should be worn at all times while on manufacturing and warehouse premises.
- Safety shoes with non-slip soles and heels should be worn. Clothing should be close fitting. Make sure laces are tied.
- Flashlights should be carried, especially when work assignments involve the upper floors or basements.
- Dust masks or properly rated respirators should be worn in dust-laden environments.
- If there is a need to use a protective device that has not been supplied or if there are safety concerns, notify a supervisor.
- While in the establishment, make sure equipment is secure during transit. A pen in a shirt pocket may fall out during the inspection and may fall into the firm’s equipment or product. A probe, flashlight, or folder may slip or fall during climbing or conducting the inspection. This may cause personal injury or injury to other employees.

AWARENESS

An inspector must not enter a grain elevator, grain mill, warehouse, railroad tank/car, or silo unless the facility’s supervisory personnel have been alerted as to his/her presence and the location where he/she will be working. Workers in the area should know who an inspector is and where he/she will be working or planning to work, and what he/she will be doing. Inspectors must not enter areas where they have no official purpose.

Plant, elevator, mill and warehouse fires are not uncommon. Know the location of exits, telephones, and first aid equipment, and especially emergency evacuation routes and procedures. Read and follow all warning signs.

Construction and maintenance work is often being performed during business operations in all plants. This activity may increase the possibility of fire or other mishaps. Keep a safe distance from construction and maintenance activities.

When entering an elevator, mill, or warehouse from bright outside light, vision may be temporarily impaired. Stop and let your eyes adjust before continuing the inspection. Be aware of the surroundings. Avoid stepping on manhole covers since they may slide from underfoot.

Be conscious of the machinery being used in the vicinity. Observe conditions surrounding the various products to be sampled, with emphasis on the danger of front-end loaders, hopper and tank cars, forklifts, conveyor belts, motor drives, mixers or blenders, welding and cutting equipment, drag and screw conveyors, falls from heights and electrical equipment. Stay clear of machinery, whether it is operating or not. The “dead” machinery may be started by a remote control switch located in another part of the plant. Do not sit or step on a motionless conveyor belt. Cross over conveyors only on cross bridges or walk around the belt end.

Watch for wet floors. Dust caused by loading or unloading feed, fertilizer, or related products can mix with the moisture on the floors, making them extremely slippery and hazardous.

When the air is dust laden, the ability to see is reduced. This can be dangerous. In this environment, protect both eyes and respiratory system with the proper equipment.

High pressure air lines must not be used to blow dust from clothing or the body. Foreign matter such as metal fragments, oil, or water can be blown under the skin or into eyes, causing a painful or serious injury.

Grain dust is extremely dangerous, because it is highly explosive, and may cause loss of life and property. There should be NO SMOKING at any time in an elevator, mill, or facility. Additionally, flash attachments to cameras or other equipment that generates sparks may ignite a dust explosion. Therefore, the concentration of grain dust in the atmosphere should be monitored for explosive levels. It is imperative that inspectors discuss their needs with facility staff prior to entering a facility with airborne dust concentrations that might be explosive.

Grain elevators are fumigated frequently. Request the fumigation schedule prior to entering or inspecting the elevator.

MAN-LIFTS AND CAGE-TYPE ELEVATORS

Most mills and elevators have elevating devices to transport personnel between working levels. They are normally cage-type elevators or continuous vertical belt-type lifts. Do not use man-lifts

or elevators for emergency evacuation of the plant. Power failure or shutdown will cause equipment to stop, possibly trapping occupants.

CAGE-TYPE ELEVATORS

The cage-type elevator is similar to a passenger elevator, except much smaller. When using the cage-type elevator, keep the door closed, and operate it per the posted instructions. If there are no posted instructions, request instructions from elevator or plant personnel. The maximum load capacity must be posted in the elevators and observed by all persons using the elevators.

MAN-LIFTS

Never attempt to ride a man-lift without getting the proper instruction in its operation. When riding an endless belt man-lift, always take the following precautions:

- Face the belt.
- Keep feet firmly on the steps.
- Hold on to the hand holds with both hands.

Freight, packaged goods, or sampling equipment must not be carried or handled on any man-lift. Only tools which fit entirely within a pocket, backpack or tool belt should be carried on man-lifts.

LADDER SAFETY

Take the following precautions when using ladders:

- Never use a ladder that has cracked rails or rungs or has slivers on rails.
- Never use a portable straight ladder that is not equipped with safety feet, unless the ladder is securely fastened in place.
- Always climb and descend a ladder facing the rungs and rails.
- Do not climb movable straight ladders unless the foot of the ladder is about one quarter of the ladder length away from the wall.
- Use only a ladder for climbing; use of chairs, boxes or other makeshift ladders invites injury.
- Always use a ladder with safety feet to enter a boxcar or truck. Do not jump from a boxcar or truck.

LIFTING SAFETY

Never attempt to lift an object that is too heavy to handle alone. Get assistance to lift heavy objects. When lifting heavy objects, make sure to follow these safety precautions:

- Get close to the load.
- Keep your back vertical, bend your legs.
- Lift slowly, feel the load react through your legs.
- If needed or warranted, use a proper back support and lift belt.

MACHINE AND EQUIPMENT SAFETY

When working around machinery, always take the following precautions:

- Never attempt to operate any machinery.
- Never remove a machinery guard or shield on a piece of equipment while it is running. Guards must never be removed unless absolutely necessary for equipment inspection. If guards are removed, steps need to be taken to ensure the equipment is not started and the guards are replaced promptly once the inspection is complete. Some agencies do not permit removal under any condition. If an emergency arises, be prepared by discussing the topic with a supervisor.

SAFETY SIGNS

Respect all safety signs in the plant; they are posted for everyone's safety. Failure to obey signs can cause injury. The words "caution" and "warning" are there for a reason. Pay attention to directions provided.

ELECTRICAL SAFETY

Never tamper with electrical equipment. Electricity can kill quickly.

CONFINED SPACES

Confined space entry has resulted in more deaths and injury than any other source in the industry, therefore, it is essential to recognize and carefully evaluate the situation prior to entry. See the discussion on "Hazards and Hazardous Materials" starting on page 15 of this Chapter.

The Occupational Safety and Health Administration[1] defines a confined space as a space that:

- Is large enough and so configured that an employee can bodily enter and perform assigned work;
- Has limited or restricted means for entry or exit (for example, tanks, vessels, silos, storage bins, hoppers, vaults, and pits are spaces that may have limited means of entry.); and
- Is not designed for continuous employee occupancy.

In addition, any space that meets the above criteria, and has a depth of 4.5 feet or more from the plane of entry to the plane upon which the worker will perform their work or when a person's head or feet pass the plane of entry or any other opening is considered a confined space.

A confined space is particularly hazardous when it meets one or more of the following criteria:

- Contains or has a potential to contain a hazardous atmosphere.
- Contains a material that has the potential for engulfing an entrant.
- Has an internal configuration such that a person could be trapped or asphyxiated by inwardly converging walls or by a floor which slopes downward and tapers to a smaller cross-section.
- Contains any other recognized serious safety or health hazard.

SAFETY WHILE SAMPLING

Prior to sampling, assess the conditions to be encountered when inspecting trucks, rail cars or storage areas. Be cognizant of fumigant warning-agent odors; however, remember that some toxic fumigants have no odor. Rather than take any chances, check with management to eliminate any risk of exposure. DOT regulations and pesticide labels usually require that warning signs be placed on rail cars containing fumigated commodities. If there is a fumigant notice on the car, especially if it has a recent date (3 days or less), or if you detect a fumigant odor, do not open it. Notify the firm management to have a qualified person determine if it is safe to open the car. The firm's qualified person must open the doors on both sides of the car and allow the car to air out for a prescribed length of time before allowing anyone to enter. Remember, some fumigants may not have a detectable odor, but are still a hazard.

Do not enter trucks, rail cars, or storage areas during the application of these materials, or enter where the materials have been applied unless the atmosphere has been certified safe by a competent person.

[1] 29 CFR §1910.146.

SAMPLING NEAR TRUCKS AND TRAILERS

Sampling around moving trucks and trailers presents a hazardous working climate. The key factor to prevention of accidents in this area is alertness. Stay constantly aware of moving vehicles and the fact that drivers can be careless. Follow these safety guidelines for sampling trucks and trailers:

- Be sure that the driver knows that someone is sampling his load so that he will not move the truck until sampling is completed. It may be a good idea to chock or block the wheels of the truck or trailer.
- If a fumigant has been applied, reread physical hazards statement on the product label or the MSDS sheet, prior to sampling.
- Use a ladder to get into and out of trailers. If the ladder is slick, wipe it off with paper towels or a cloth prior to ascending.
- Always carry or lift probes and other equipment into trucks and between units. Never toss or throw equipment.
- Do not ride on running boards or crawl under trucks or trailers.
- Always be alert and watch for moving vehicles.
- On van-type trailers, the driver is required to open doors. Always check the security of the doors before entering.

When probing, always be alert for hidden obstructions such as cross braces and bars as well as the sides and bottom of the trailers. Hitting such obstructions with a sudden force can cause serious injuries as well as damage to the trailer and probe. To prevent such occurrences, do not put weight onto the probe from a standing or running position.

Always be alert for overhead obstacles. Power lines, lights, building overhangs, and other potential hazards can cause severe injury. Stay alert.

SAMPLING RAIL CARS

Railroads are always hazardous work environments. Personnel performing sampling on boxcars and hopper cars must be very careful. Minimize the possibility of an accident or injury by knowing and observing the rules of safety.

Notification is required when entering any boxcar or hopper car in a railroad yard or car siding. Inspectors who are part of a team or by themselves must be certain that appropriate personnel are aware of where they are working and the length of time it will take to obtain the samples. Different departments may have specific rules regarding the entry into the box car. Consult a supervisor for all necessary instructions. Persons that must be notified include:

- Manager of the plant.
- Person in charge of unloading.
- Track-master responsible for the movement of trains.

The person or persons notified prior to sampling of boxcars or hopper cars must also be notified when you are finished.

Railcars to be sampled are classified as either boxcars or hopper cars. The physical characteristics of the two are completely different and the hazards involved are unique. Therefore, each will be covered separately.

BOXCARS

First, assess the boxcar's condition. Next, notice the seal that must be broken. A cutting tool such as side cutters or a pry bar must be used to cut or break the seal. Wear protective eye wear when breaking the seal. Seal locking mechanisms often fly apart as they are broken and may also be sharp and cut hands or skin.

Opening and closing car doors can be hazardous. When using a pry bar, push the door away from you. Never stand beside the door; it may come free of its track and fall.

Note the condition of the grain door and watch for protruding nails and steel strapping. Place sampling equipment on the door sill and climb into the car. Never throw sampling equipment into the car before entering.

Check the inside of the car for protruding nails, bolt heads, etc. Older boxcars may have wire, rods, or wooden cross braces; use care not to strike them.

When probing, do not place excessive body weight onto the probe from a standing position. Rib or shoulder injury may occur if the material or product is shallow and the end of the probe strikes the floor.

Use the same care in dismounting from the car as when entering. Do not throw sample or equipment from the car; it could hit someone below or damage the equipment or sample.

HOPPER CARS

The hopper car is a special purpose type carrier that requires sampling from the top through either individual hatches or a continuous opening down the center of the car. Because of its unique construction and the longer and heavier equipment required for sampling, it is probably more dangerous to sample than a boxcar.

The first thing to look for when approaching a hopper car is electric power lines above or close to the car. Inspectors have been seriously injured as a result of the sampling probe coming in

contact with electric lines. If lines are present, extreme care and caution must be used during the sampling operation.

Check the condition of the car's ladders. If a ladder is damaged, loose, or bent, go to the other end of the car and check for a more secure ladder. Ascend the ladder carefully.

Watch for the approach of a switch engine or switched car while working atop hopper cars. If, during sampling, the car is moved and there is no time to get down from (or out of) the car, kneel or sit down to lessen the possibility of falling from the car.

Care must be used in breaking seals. Many lids and hatch covers are quite heavy and require proper lifting techniques. A back brace will help prevent injury. When probing is started, care must be taken not to probe into the sides of the hopper car bottoms; this will cause the probe to stop suddenly.

While atop hopper cars, be especially careful if there is spilled, loose, or wet product or dust. In winter, there may be ice, frost, or snow. Safety belts are required by OSHA regulations to enter a hopper car since it is a confined space. It is the inspector's responsibility to decide whether or not the condition presents such a hazard as to deem the car too dangerous for sampling at that time.

High winds during the sampling of a hopper car can blow the hatch covers on the inspector or blow the inspector or his/her equipment off of the car. Such conditions are considered too hazardous for sampling activities.

Never sample a hopper car from above when any partial or incomplete unloading is occurring. Hopper bins may present a false "skin" or layer that can break and trap persons attempting to collect samples. It is a potential deadly situation. Notify the person in charge of unloading when you are finished sampling.

SAMPLING BINS AND TANKS

Be alert and take proper safety precautions in plants, silos, bins, pits and any closed areas where bulk products are stored and asphyxiation hazards exist. If certain products are improperly stored, improperly handled, or decomposing, dangerous amounts of carbon dioxide or other gases may deplete the oxygen supply in these areas. Never enter closed bins or tanks for the purpose of obtaining probe samples without prior approval of a supervisor. Prior to entering a bin or tank, the inspector must determine that the oxygen content of the bin or tank is sufficient to sustain life. Do not enter fumigated or treated bins or tanks until a "Gas Free Certificate" or an "Entry Permit" (with multiple confined space requirements) has been posted.

When it is necessary to enter a bin, advise the facility supervisor and workers in the bin area before entering, and again when the bin is cleared. Turn-heads, spouts and trippers must not be set for that bin. Before entering a bin, it must be inspected first from the top to make sure that no grain is hung up. Do not jump down on top of the grain -- there may be a cavity caused by

crusted grain which could break. Do not enter bins without a proper safety belt. People have lost their lives by entering bins without taking the proper precautions.

SAMPLING BAGGED OR PACKED PRODUCTS

Stay alert when collecting samples during the bagging or packaging process, and when samples are stored in a warehouse. Remove any loose-fitting jewelry. Check-weighing requiring the removal of bags or packages from the line can cause injury. Be alert for the movement of forklifts used to move the commodity. Stacked paper or polypropylene bags can shift or may fall easily. When sampling stacked bags or containers on pallets and a ladder is required, ensure the ladder provides stable footing before using.

SAMPLING BULK BAGGED PRODUCTS (LARGE VOLUME BAGS)

One of the trends in some industries is to go to large 2,000-pound bags instead of the typical 50-pound package. Frequently, these bags are transported in a frame and tend to be double lined. The outside bag is a tough canvas or plastic material while the inner bag is a simple plastic liner. Typically, these bags will be six or seven feet tall and can only be accessed from the top. If a ladder is needed, secure it properly before attempting to sample. Also, be aware that the outer material is slippery and weight applied to a stack may cause the stack to shift or slip and induce a hazardous situation.

HAZARDS AND HAZARDOUS MATERIALS

Chemical compounds are commonly used to control or eliminate insect infestations in agricultural products or in containers used to store or transport these products. Such chemical compounds can present a serious hazard when used in an indiscriminate manner or when individuals disregard necessary safety precautions through ignorance or poor judgment. No individual is immune to the toxicity of these chemicals. There may be many different reactions to exposure to these toxic chemicals, such as a reduction in the body's natural resistance that can compound the effect of the exposure.

Chemical applications to agricultural products or to containers used to store or transport these products may be separated into three categories, each offering a different degree of hazard. When describing a chemical application of a commodity or container, proper terminology must be used, as it can indicate the degree of hazard involved in the application.

The following lists the types of hazardous pesticides that are commonly encountered during pesticide inspections:

- **Contact-type pesticides**—Active ingredients such as malathion and pyrethrum are contact-type pesticides (i.e., their effectiveness depends upon the insects coming in contact with the material). Contact pesticides can be applied directly to the commodity or used to eliminate an infestation within a container. Inspectors must not enter or remain in an area while these materials are being applied as sprays or until all vapors or mists have settled from the atmosphere. Vapor contact and absorption through the skin and the vapor or mist entering the respiratory system can cause ill effects.
- **Smoke and fog-type pesticides**—Resmethrin, piperonyl butoxide, pyrethrins, malathion and diclorvos (DDVP) are among the active ingredients typically used in foggers. These pesticides are used to treat unoccupied residential, greenhouse and commercial areas and transportation equipment. Such areas must not be entered until the time specified in the Directions for Use has passed. Most fogger propellants are flammable.[2]
- **Fumigant pesticides**—Use of fumigants in elevators, mills, and warehouses is not unusual. If a fumigant or unidentifiable odor is detected, check with plant personnel and determine the source of the odor. Fumigants are hazardous to breathe, even at low concentrations. Spray treatments of grain and storage areas within facilities, elevators and mills are common. Avoid breathing vapor from sprays. If accidental contact is made, wash the area of the body contacted with mild soap and water. Remove and thoroughly wash clothing, including shoes. Report mishaps to the supervisor and seek the recommendation of a physician.

  Fumigants are normally liquid or solid chemical compounds which, when released into the atmosphere, readily turn to the gaseous state. These products are extremely toxic to humans and must be handled or dealt with using extreme caution. When a commodity has been fumigated, a percentage of the fumigant is absorbed by the commodity. This fumigant will be desorbed during the aeration process at a retarded rate. After a container has been fumigated, aerated, and resealed, it is possible for a dangerous concentration of the fumigant to build up within the container. When a certificate is issued by a competent person, perform the inspection duties within a two-hour period after testing and issuance of the certificate, provided that the fumigated area has remained open to the atmosphere. In the event the two-hour time period has been exceeded or the container sealed, a new test and certificate by the competent person is required.

Do not enter storage containers during the application of these materials or enter a container where the materials have been applied unless the atmosphere within the containers has been certified safe by a competent person.

[2] PR Notice 98-6 (6 pp, 17 K) - Flammability Labeling Requirements for Total Release Fogger Pesticides.

Residues remaining on container surfaces, after the application of smoke and fog or fumigant type pesticides, are more toxic than the contact-type residues. When performing vessel storage examinations, inspectors may pick up residue on their hands while climbing or descending ladders. Do not eat, smoke or use toilet facilities until hands are thoroughly washed with soap and water.

EXPOSURE TO HAZARDOUS MATERIALS

Indications of exposure to a chemical compound include, but are not limited to, the following symptoms:

- Skin irritation (rash, burning sensation, dryness and sensitivity).
- Watering of the eyes (also burning sensation).
- Dryness of the nasal passages.
- Coughing.
- Shortness of breath.
- Congestion in the chest.
- Nausea and vomiting.
- Light-headedness.
- Intoxication.
- Ashen complexion.
- Agitation.

Make sure there is easy access to the emergency telephone numbers such as police, fire department, medical doctor or hospital, rescue service or state or local poison control center. Inspectors must stay aware of their physical condition and surroundings. Horseplay, in any form, is dangerous and strictly prohibited.

Do not take chances where chemical compounds are involved.

If the inspector has any reason to suspect that an inspection poses a potentially harmful or fatal exposure, check with the company's responsible officer. If, after checking, the inspector still has concerns about the potential for harm, he/she must not perform the inspection. Inspectors should consult with their supervisor when such conditions are found.

Report to a supervisor all injuries, no matter how minor they may seem, as well as unsafe conditions and unsafe acts that might be the cause of an accident.

HAZARDS

Accidents, occupational illness and fatalities can occur through asphyxiation, fire and explosion, exposure to substances, falls, electrocution, and a host of other specific hazards. Flammable atmospheres can result from an enriched oxygen atmosphere, vaporization of flammable liquids, concentrations of combustible dust, workplace byproducts or desorption of chemicals from surface coatings.

Too much oxygen, even a small percent above the 20.9 percent normally found in our atmosphere, will cause an increase in the range of flammability. A flammable atmosphere is created when the oxygen-combustibility mixture is neither too rich nor too lean for combustion to occur. If inadequate ventilation occurs, flammable gasses such as propane, methane or hydrocarbons can be trapped in a confined space. Since a number of these vapors or gases are heavier than air, they may sink and become concentrated at the lower level of the confined space.

Combustible dust concentrations can often be found in grain elevators and silo storage areas.

ENTRY AND EXIT

The size of the entry orifice must be taken into account when considering rescue actions. Barriers to entry, and ladders or the lack thereof, must also be considered. Workers may fall off ladders, develop claustrophobia or become lodged in the entry orifice.

INSPECTOR RESPONSIBILITIES

Inspectors must report any hazardous conditions in connection with confined space entry or any safety equipment defects to the facility manager immediately. **Without exception, no inspector shall enter a confined space unless it is absolutely necessary, and only when two or more other persons are present, in case an emergency should arise.**

ENVIRONMENTAL BIOLOGICAL HAZARDS

The risk to the inspector of contracting disease from pathogens is extremely small. However, steps should still be taken to minimize exposure during an inspection. Note that in April of 2016 EPA issued Biosecurity Procedures for Visits to Livestock and Poultry Facilities.

BE AWARE OF PATHOGEN HAZARDS DURING AN INSPECTION

Walking in or around buildings or crawling beneath a building can bring a person into contact with pathogens, stinging or biting arthropods and insects. Rodent, bird and bat feces can be encountered in any attic, crawlspace, garage, basement or feed mill. Bird feces can be found accumulated on the ground outside and on rooftops.

Bacteria are everywhere in the soil and on every surface. Pathogenic bacteria are most likely encountered where animal feces, decaying food, or decaying animal matter is located. Mishandling rodent or animal carcasses also brings contact with potentially pathogenic bacteria.

Histoplasmosis risk is greatest where bird or bat feces have accumulated in or on top of soil. *Cryptococcoses* is most likely in accumulations of pigeon feces in attics, false ceilings, and warehouses.

Hantavirus contact is most likely in areas where rodent activity is detected and there is a large amount of droppings and/or the smell of urine. Attics, closets, storerooms, cellars, basement, garages and warehouses must all be viewed for the potential for encountering mice and other rodents. Hantavirus risk is extremely low.

Bee and wasp stings can occur upon accidental stumbling into a nest of these social insects. Spider bites can occur when putting on shoes or clothes in which the spider is hiding or when moving a board, landscape timber or other item under which the spider is hiding.

PROTECTING AGAINST ENVIRONMENTAL PATHOGENS

Appropriate PPE needs to be worn by each person who enters an area where pathogens may be encountered. PPE that may offer appropriate protection include respirator, protective gloves, unvented goggles, Tyvek coveralls, leather boots/rubber overshoes (or rubber boots), disinfectant soap, disinfectant sprays, and insect repellent. Additionally:

- Recognize areas of potential risk, including: numerous rodent droppings; bird droppings on soil, on floors, in attics, etc.; excessively dusty conditions; excess decaying food debris or other decaying organic matter; presence of dead rodents, birds, or other animals present (presence of blow flies and fly pupae); evidence of raccoons, possums, or skunks living in the structure; and older buildings.
- Wear a respirator, eye protection, and protective gloves in suspect environments. Persons who have facial hair (i.e. beard) will not achieve a tight enough seal with any respirator.
- Keep all cuts carefully bandaged, especially on hands. Wear gloves.
- Spray rodent droppings, rodent nests, and dead rodents with a disinfectant spray prior to handling or entering a suspect area. Other dead animals must also be treated with disinfectant before handling. Use a pump type sprayer to dispense the product; an aerosol product may disturb small particles and increase exposure.
- Never attempt to sweep up or vacuum animal droppings, as dust will become airborne. Spray such areas with disinfectant, let sit for a short period prior to wiping up with rags or paper towels (if they have to be handled at all).

- Remove and dispose of disposable gloves, Tyvek coveralls, and booties immediately after exiting the contaminated area. Continue to wear a respirator and gloves if possible when removing coveralls as dust on the coveralls could become airborne.
- Immediately after removing contaminated items, place them in a plastic bag, spray additional disinfectant solution in the bag, tightly-seal the bag, and properly dispose of the bag.
- Disinfect nitrile, rubber, or latex gloves in an approved disinfectant solution. Rinse thoroughly.
- While wearing protective gloves, clean the respirator face piece with disinfectant solution and rinse thoroughly. Store the respirator in a sealed Ziploc-type bag.
- When walking or working in areas where ticks could be present (wooded areas, tall grass), tuck pant legs into boots or socks and spray pant legs with insect repellant (unless taking residue samples). It should be noted that if collecting samples or entering an area where samples may be collected, the use of insect repellants may cross-contaminate the sample.
- Avoid entering any area where a dog or wild mammal may be present. Any animal acting strangely must be avoided.

COMMON PATHOGENS

An inspector should be aware of *some* common pathogens and their epidemiology in order to take appropriate precautions during inspections.

- *Salmonella*
    - A bacterium.
    - Present in the surrounding environment, including the soil. Especially common where decaying food materials are present.
    - Causes food poisoning. Sometimes fatal depending on the type and lack of treatment.
    - Enters the body by ingestion, usually in infected food or from contact with unwashed hands.
- *Staphylococcus*
    - A bacterium.
    - Present in the surrounding environment, including the soil. Especially common where decaying food materials are present.

- Causes infections in cuts and also in eyes. Severe flesh necrosis can occur. Fatalities are rare except if the bacteria enter the bloodstream (septicemia).
- Enters the body through breaks in the skin caused by cuts, abrasions, and blisters.

- *E. coli*
  - A bacterium.
  - Present in human and animal feces.
  - Causes severe food poisoning. A particular strain, not likely to be encountered, can be fatal.
  - Enters the body by ingestion of contaminated food or from contact with unwashed hands.
- *Histoplasma capsulatum*
  - A fungus.
  - Present in accumulated bird, chicken, and bat feces in contact with the soil. The feces enrich the soil allowing the fungus to proliferate.
  - Spores become airborne when feces are disturbed.
  - Causes respiratory illness (histoplasmosis) and also blindness. Can be fatal, but fatalities are rare.
  - Enters the body by inhalation of fungal spores and through the eyes.
- *Cryptococcus neoformans*
  - A pathogenic yeast (fungus).
  - Present in accumulated pigeon feces within buildings. Does not need to be in contact with the soil.
  - Spores become airborne when feces are disturbed.
  - Causes respiratory illness (cryptocaccosis). Can develop into cryptococcal meningitis that takes the form of severe headaches, vomiting, vertigo, and dizziness. Most serious to persons with existing lung disease, diabetes, Hodgekin's lymphoma or leukemia.
  - Enters the body by inhalation of fungal spores.
- Hantavirus
  - Biosafety Level 4 virus. Twelve different Hantaviruses have been discovered to date but only one type is confirmed to cause human disease.

- Carried by the white footed mouse or deer mouse, *Peromyscus maniculatus*. Has not been found in house mouse populations. Other types of Hantaviruses have been isolated from other types of rodents, including the cotton rat and voles.
- Virus is spread through aerosolized droplets of deer mouse urine and on microscopic particles of dust infected by urine or associated with deer mouse droppings. Handling deer mouse carcasses also poses a risk.
- Causes Hantavirus Pulmonary Syndrome (HPS), which causes a victim's lungs to fill with fluid, sometimes causing cardiac arrest.
- Deer mice are found most often in areas bordered by woods and fields.

- Rabies
  - A virus.
  - Spread by the bite of an infected animal or by improper handling of infected animal carcasses.
  - In urban areas, skunks, raccoons, coyotes, and dogs are the primary reservoirs.
  - Affects the central nervous system. Always fatal unless treated.
- *Borrelia burgdorferi* (Lyme Disease)
  - A bacterium.
  - Carried and spread by various ticks but especially the deer tick, Ixodes dammini.
  - The reservoir in the wild is the deer mouse.
  - Causes a myriad of symptoms depending on which body system is attacked. Attack of the nervous system is the most serious but can cause arthritic-like symptoms. If undiagnosed and untreated for too long, damage to the body may be irreversible.
- Insect and arthopod stings
  - Effects due to venom from bees, wasps, scorpions, and some ants.
  - General swelling and localized reactions are normal.
  - Sensitive individuals can lapse into anaphylactic shock which can be fatal.
- Spider bite
  - Effects are due to the venom of black widow spiders and brown recluse spiders.
  - Black widow venom affects the nervous system causing most muscle systems in the body to cramp. Rarely fatal except in young children and the elderly.

- Brown recluse venom causes collapse of microscopic blood vessels in area of bite. Lack of blood and nutrients in affected area leads to tissue death and necrosis. Secondary Staphylococcus infections can lead to more serious necrosis and possibly to loss of the affected limb.
- Plastic surgery is sometimes necessary depending on the seriousness and location of the bite.
- Black Widow –



- Brown Recluse –



TRAVEL SAFETY

Inspectors may be required to travel several thousand miles a year in order to cover assigned areas or territories. This may be in an Agency-owned vehicle or in the inspector's own vehicle. Regardless, a few key safety points or checks will prove valuable in preventing or minimizing breakdowns and accidents.

VEHICLE SAFETY

Before starting the vehicle, make a quick check of the vehicle's condition. Pay close attention to the tires. Worn tires, low tire pressure or punctures in tires may cause a blowout while on the road. Agricultural establishments often will have metal parts, screws, nails, or similar items in the driveway areas of the firm or business. As such, it may be wise to make a visual inspection prior to leaving inspected a firm or business.

It is also important how equipment is arranged in the vehicle. An inspector is required to carry a vast amount of equipment and supplies. This equipment needs to be arranged and secured in

case of a quick stop or collision. In such a case, an unsecured piece of equipment may act as a projectile inside the car. Therefore, attention must be paid to how equipment is stored and secured. Take time and make sure everything is in proper position to avoid unnecessary risks.

In addition, inspectors may be required to transport hazardous materials or samples as part of their duties. Ensure that samples are stored in a manner that would not create a hazard if broken, spilled, or otherwise released. Also, vapors from these products may be dangerous and must not be stored in the passenger compartment of the vehicle. Hazardous materials must also be properly packaged to prevent breakage and these packages must be secured to prevent them from rolling around.

Vehicle maintenance cannot be overstated. Depending upon EPA and/or GSA guidelines, make sure to routinely check the maintenance of the vehicle. Tires, brakes, fluids, hoses, belts, etc., must all be checked on a regular basis. Inspectors often find themselves in rural or unpopulated areas. While no examination will guarantee unwanted breakdowns, there is a good chance of minimizing them.

Once in the vehicle, always wear a seat belt.

PERSONAL SAFETY

Always carry a first-aid kit complete with bandages, topical antibiotic dressings and antiseptic cleansers. Cuts, scrapes, and bruises are commonplace when working around equipment. Be prepared to treat them rapidly and effectively.

It is advisable to keep current with immunizations. Pay particular attention to tetanus shots and periodical boosters. Discuss with your physician or the Public Health Service physician potential side effects of new medications, such as nausea, drowsiness, or ability to perform your job safely. Read warnings on over-the-counter medication.

Avoid, if at all possible, becoming involved in a confrontational situation. If, however, a situation becomes confrontational, the inspector should exit the inspection site and contact their management and/or the U.S. Marshal Service, police, etc. Obtain a warrant before re-entering the site to continue the inspection.

LODGING SAFETY

When arriving at a motel or hotel, try to park in well-lit areas. Be aware of persons in parking garages and lots. When parked, lock the vehicle. It is best not to leave any type of valuables in the vehicle. If valuables must be stored in the vehicle, try to cover or hide them. Depending on weather conditions (heat and cold), and for security and to ensure chain-of-custody, it may be necessary to remove samples from the vehicle and store them in the motel/hotel room or in a secure area.

Be aware of the people in the lobby when checking in. Pay attention to the surroundings.

Once in the room, pay attention to the security mechanisms provided. If dead bolt locks and chains are in place, use them.

Locate the nearest exit in case of fire or an emergency. Usually, evacuation instructions will be posted in the room. If not, make a visual check of how to get out safely.

Use the peep hole in the door to visually identify persons knocking on the door. If the person claims to be a hotel or motel employee, get the person's name and verify via telephone with the front desk before letting the person into the room. If the person is indeed an employee, they will not mind.

Check your room for pests and unsafe conditions. Bedbug infestations in motels and hotels are increasingly common. Check bedding, closets, dresser drawers, etc. for these pests and other pests before completely settling into the room. Any pests should be brought to the attention of the motel/hotel management. For more information on how to identify bedbugs go to: https://www.epa.gov/bedbugs/bed-bugs-appearance-and-life-cycle.

CHAPTER THREE
PESTICIDE LAW, POLICY AND COMPLIANCE STRATEGIES

CONTENTS

Statutory Authority For Pesticide Regulation 2
Regulations 2
Compliance and Enforcement Policies and Strategies 3
Standard Operating Procedures 4
Pesticide Registration 4
Pesticides Requiring Registration 4
Products Not Considered Pesticides 5
Pesticides Exempt from Registration 5
Unregistered Pesticides 6
Supplemental Distribution (40 C.F.R. §152.132) 7
Section 24(c) Registrations (40 C.F.R. §§162.150-162.156) 8

PESTICIDE LAW, POLICY AND COMPLIANCE STRATEGIES

STATUTORY AUTHORITY FOR PESTICIDE REGULATION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act) was first passed in 1947 and has been amended numerous times, most recently by the Pesticide Registration Improvement Extension Act of 2012. FIFRA provides EPA with the authority to oversee, among other things, the registration, distribution, sale and use of pesticides. The Act (7 U.S.C. §§136-136(y)) applies to all types of pesticides, including insecticides, herbicides, fungicides, rodenticides, antimicrobials and devices. FIFRA covers both intrastate and interstate commerce. For an overview of FIFRA, go to Summary of the Federal Insecticide, Fungicide and Rodenticide Act.

REGULATIONS

The pesticide regulations are codified and found in Title 40 of the Code of Federal Regulations, Protection of Environment, Chapter 1, Environmental Protection Agency, Parts 150 to 189.[1] Specifically:

40 C.F.R. Part 152	Pesticide registration and classification procedures
40 C.F.R. Part 153	Registration policies and interpretations
40 C.F.R. Part 154	Special review procedures
40 C.F.R. Part 155	Registration standards and registration review
40 C.F.R. Part 156	Labeling requirements for pesticides and devices
40 C.F.R. Part 157	Packaging requirements for pesticides and devices
40 C.F.R. Part 158	Data requirements for pesticides
40 C.F.R. Part 159	Statements of policies and interpretations
40 C.F.R. Part 160	Good Laboratory Practice Standards
40 C.F.R. Part 161	Data requirements for registration of anti-microbial pesticides
40 C.F.R. Part 162	State registration of pesticide products
40 C.F.R. Part 164	Rules of practices governing hearings under FIFRA arising from refusals to register, cancellations of registrations, chances of classifications,

[1] https://www.govinfo.gov/app/collection/cfr/2018/title40/chapterI/subchapterE

	suspensions of registrations and other hearings called pursuant to section 6 of the Act
40 C.F.R. Part 165	Pesticide management and disposal
40 C.F.R. Part 166	Exemption of Federal and State agencies for use of pesticides under emergency conditions
40 C.F.R. Part 167	Registration of pesticide and active ingredient producing establishments, submission of pesticide reports
40 C.F.R. Part 168	Statements of enforcement policies and interpretations
40 C.F.R. Part 169	Books and records of pesticide production and distribution
40 C.F.R. Part 170	Worker protection standard
40 C.F.R. Part 171	Certification of pesticide applicators
40 C.F.R. Part 172	Experimental use permits
40 C.F.R. Part 173	Procedures governing the rescission of state primary enforcement responsibility for pesticide use violations
40 C.F.R. Part 174	Procedures and requirements for plant-incorporated protectants
40 C.F.R. Part 176	Time-limited tolerances for emergency exemptions
40 C.F.R. Part 178	Objections and requests for hearings
40 C.F.R. Part 179	Formal evidentiary public hearing
40 C.F.R. Part 180	Tolerances and exemptions for pesticide chemical residues in food

COMPLIANCE AND ENFORCEMENT POLICIES AND STRATEGIES

FIFRA inspectors may find the following pesticide policies and enforcement documents to be relevant:

- Pesticide Management and Disposal Compliance Strategy.
- Interim Policy on Inspection Report Timeliness and Standardization
- Guidance on Investigating Pesticide Related Bee Incidents
- FIFRA Compliance Monitoring Strategy
- Fact Sheet on Pesticides Sales in eCommerce
- Digital Image Guidance
- Use of Mobile Field Inspection Tools.
- Role of Inspector in Providing Compliance Assistance.

- Final Policy Affirming the EPA Authority to Access Facilities and Conduct Inspections Without Providing Personally Identifiable Information.
- Fumigation Toolbox.
- Worker Protection Standard Guidance.
- Antimicrobial Sampling Guidance.
- Pesticide Registration (PR) Notices.
- Enforcement Response Policy for FIFRA Container/Containment Regulations Appendix H (March 2012).
- FIFRA Enforcement Response Policy (December 2009).
- Enforcement Response Policy for FIFRA Section 7(c) (May 2010).
- Final Interpretive Rule.

Standard Operating Procedures

All EPA regional and program offices which conduct field activities have implemented a field quality management system in accordance with the EPA Quality Assurance Field Activities Procedure (CIO 2105-P-02.0). All EPA field activities, including FIFRA compliance inspections, must be conducted in accordance with relevant field activity procedures.

PESTICIDE REGISTRATION

FIFRA section 3 states that no person in any state may distribute or sell to any person a pesticide that is not registered, unless exempted by section 3(b). Implementing regulations at 40 C.F.R. Parts 152-167 establish the requirements for product registration. Inspectors who wish to learn more about pesticide registration procedures may consult:

- Pesticide Registration Manual.
- EPA's pesticide registration portal.

Pesticides Requiring Registration

A product is required to be registered if any or all the following conditions exist:

- A product meets the definition of a pesticide in section 2(u) of FIFRA and 40 C.F.R. §152.15.
- The product's labeling and other material make pesticidal claims.

- A product is represented in any manner that implies it is being used as a pesticide.
- The product contains one or more active ingredients and has no commercially valuable use as distributed or sold other than use for pesticidal purpose or use for manufacture of a pesticide.
- The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used or is intended to be used for a pesticidal purpose.

Products Not Considered Pesticides

Certain products do not meet these criteria and are not considered to be pesticides (40 C.F.R. §§152.8 and 152.10). These products include:

- Deodorizers, bleaches, and cleaning agents.
- Products not containing toxicants, intended only to attract pests for survey or detection purposes, and labeled accordingly.
- Products intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants, such as certain pruning paints for trees.
- Products intended for use only for the control of fungi, bacteria, viruses or other microorganisms in or on living man or animals, and labeled accordingly.
- Products intended for use only for control of internal invertebrate parasites or nematodes in living man or animals, and labeled accordingly.
- Products intended only to aid the growth of desirable plants.

Pesticides Exempt from Registration

Other classes of products are considered to be pesticide products but are exempt from registration (40 C.F.R. §152.25). These products are, however, subject to the misbranding provisions of FIFRA, which require adequate labeling and identification of products to ensure safe shipment and use. Exempt products include:

- Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.
- Pheromones and pheromone traps. Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps, and pheromone traps in which those compounds are the sole active ingredient(s) (40 C.F.R. §152.25(b)).
- Preservatives for biological specimens (40 C.F.R. §152.25(c)).
- Vitamin hormone horticultural products consisting of mixtures of plant hormones, plant nutrients, inoculants or soil amendments that meet all of the criteria in 40 C.F.R. §152.25(d).

- Products consisting of foods and containing no active ingredients, which are used to attract pests.
- Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling and needles that meet all of the criteria in 40 C.F.R. §152.25(f).
- Minimum risk pesticides. Products containing the active ingredients listed in 40 C.F.R. §152.25(g) are exempt from the requirements of FIFRA, alone or in combination with other substances listed, provided that all of the criteria of 40 C.F.R. §152.25 are met.

UNREGISTERED PESTICIDES

FIFRA inspectors may encounter unregistered products that claim to be pesticides (i.e., product advertising or labeling with statements such as "new formula kills bugs on contact") and are sold or distributed in violation of FIFRA. Inspectors that discover unregistered pesticide products should obtain product labels, samples, marketing or advertising materials and any other evidence that indicates the product is pesticidal. The inspector should include these materials and evidence in the inspection report for EPA to determine whether the product is an unregistered pesticide. If inspectors are not sure whether a particular product is a pesticide, they can call EPA during the inspection and collect evidence for subsequent EPA review.

An unregistered pesticide, or a pesticide whose registration has been cancelled or suspended may be distributed, sold or transferred as follows (40 C.F.R. §152.30):

- An unregistered pesticide may be transferred between registered establishments operated by the same producer. The pesticide must be labeled in accordance with 40 C.F.R. Part 156.
- An unregistered pesticide may be transferred between registered establishments not operated by the same producer if:
    1. The transfer is solely for the purpose of further formulation, packaging, or labeling into a product that is registered,
    2. Each active ingredient in the pesticide at the time of transfer is present as a result of incorporation into the pesticide of either a registered product, or a pesticide that is produced by the registrant of the final product, and
    3. The product is labeled in accordance with 40 C.F.R. Part 156.
- An unregistered pesticide may be distributed or sold in accordance with the terms of an experimental use permit issued under FIFRA section 5 if the product is labeled in accordance with 40 C.F.R. §172.6. In addition, an unregistered pesticide may be distributed or sold in accordance with the provisions of 40 CFR §172.3 (use of a pesticide for which an experimental use permit is not required) provided the product is labeled in accordance with 40 C.F.R. Part 156.

- An unregistered pesticide may be transferred within the United States solely for export if it meets the following conditions: (1) the product is prepared and packaged according to the specifications of the foreign purchaser and (2) the product is labeled in accordance with 40 C.F.R. Part 156.
- An unregistered pesticide may be distributed or sold in accordance with the terms of an emergency exemption under FIFRA section 18 if the product is labeled in accordance with 40 C.F.R. Part 156.
- An unregistered, suspended or cancelled pesticide may be transferred solely for disposal in accordance with FIFRA section 19 or an applicable Administrator's order. The product must be labeled in accordance with 40 C.F.R. Part 156.
- Existing stocks of a formerly registered pesticide that has had its registration canceled or suspended may be distributed or sold to the extent and in the manner specified in an order issued by the EPA. The inspector should collect production records and sale/distribution records so that EPA can verify that the products were in existence prior to the date of EPA's cancellation order.

SUPPLEMENTAL DISTRIBUTION (40 C.F.R. §152.132)

A registered product can be supplementally distributed (also known as private labels), which allows a distributor to market the product under his/her own brand name. The following conditions must be met:

- The product must have the same composition as the primary registered pesticide and must be produced, labeled and packaged in a registered establishment operated by the same producer (or under contract in accordance with 40 C.F.R. §152.30).
- The product labeling must bear the same claims as the primary product. Specific claims may be deleted if by so doing no other changes are required.
- The distributed product must not be repackaged (must remain in the producer's unopened container). However, distributors can repackage and re-label provided they are a registered pesticide producing establishment and they have a contract with the registrant for repackaging.
- The label must bear the EPA Registration Number of the primary registered product and the distributor's company number must appear as a suffix to the registration number. For example, on supplementally distributed products, the EPA Registration Number will appear as:

EPA Reg. # XXXXX-YYY-ZZZZZ

(The first part of the registration number (XXXXX) is the basic registrant's company number, the second part (YYY) is the registrant's product number and the third part (ZZZZZ) is the distributor's company number. Note, the distributor is a supplemental registrant.)

- Distributor products may bear the name and address of the distributor.

The registrant must submit an Application for Supplemental Registration of Distributor (EPA Form 8570-5) to OPP.

SECTION 24(c) REGISTRATIONS (40 C.F.R. §§162.150-162.156)

Under section 24(c), states may register a federally registered product for additional uses if a special local need exists. In addition, 40 C.F.R. §162.152 allows state registration of new formulations under certain circumstances. States must notify EPA in writing within ten working days from the date a state issues, amends or revokes a registration. Notification of state registrations or amendments to registrations include the effective date of the registration or amendment, a confidential statement of the formula of any new product and a copy of the draft labeling reviewed and approved by the state (provided that labeling previously approved by EPA as part of a federal registration does not need to be submitted). The notification of revocation of a registration by a state must indicate the effective date of revocation and state the reasons for revocation. Within 60 days after the effective date of the registration or amendment, states must submit a copy of the final printed labeling approved by the state.

EPA may request, when appropriate, that a state submit any data used to determine that unreasonable adverse effects will not be caused when it registers any use described in 40 C.F.R. §162. States are required to submit two copies of the requested data within 15 working days of receipt of this request from EPA.

The state may not issue a section 24(c) registration that requires a new food or feed tolerance.

OPP shares section 24(c) registrations with the regional offices. The inspector will have access to this product information.

CHAPTER FOUR
FEDERAL, STATE AND TRIBAL COOPERATION

CONTENTS

Background 2
Authorities 2
Authority of the States 2
State Primacy 2
The Role of Tribes 3
Referral Procedures Under FIFRA Sections 26 and 27 3
Cooperative Enforcement Agreements 4
When to Use Federal Credentials/Forms/SOPs 5
Using State/Tribal Credentials, Forms and Procedures 5
Using Federal Credentials/Forms/SOPS 5
Interagency Referrals 6
Memorandum of Understanding 6
Procedures 6
FDA and USDA Referrals to EPA 6
EPA Referrals to FDA and USDA 7
Referrals between EPA and State or Tribal Agencies 7
Interagency Response to Emergency Situations 7
Exhibit 4-1: Interagency Referral Format 8

FEDERAL, STATE AND TRIBAL COOPERATION

BACKGROUND

State and tribal pesticide regulatory agencies throughout the United States work cooperatively with the EPA to enforce federal, state and tribal pesticide statutes. This collective and collaborative enforcement effort exists due to the contributions of highly qualified and trained government officials working at each of these levels of government.

EPA provides funding and guidance to states and tribes to carry out pesticide enforcement activities to protect human health and the environment. The states and tribes, in turn, direct these resources toward efforts to address both federal and state or tribal pesticide management priorities.

Among the primary objectives of this working partnership include:

- Protecting the public and the environment by ensuring pesticide product compliance and proper use.
- Improving coordination of the federal and state or tribal pesticide enforcement program(s).
- Working together to identify challenges nationally and within the states and tribes, resolve cases and deal with the problems.
- Improving targeting of resources by tailoring the program to meet the local needs and concerns of each state or tribe.
- Providing more efficient use of resources through cooperation with state and tribal offices and personnel.

AUTHORITIES

AUTHORITY OF THE STATES

Section 24(a) of FIFRA authorizes a state to regulate the sale or use of any federally registered pesticide or device in that state, but only if and to the extent the state regulation does not permit any sale or use prohibited by FIFRA. The state may not impose labeling or packaging requirements in addition to or different from those required by FIFRA. However, Section 24(c) authorizes additional uses of federally registered pesticides under certain circumstances to address special local needs.

STATE PRIMACY

Sections 26 and 27 of FIFRA set forth the conditions under which states may receive primary enforcement responsibility (primacy) for pesticide use violations and authorizes the Administrator to override or rescind primacy in certain situations. On January 5, 1983, EPA published a Final Interpretive Rule in the Federal Register to provide operational guidance for FIFRA sections 26 and 27. Procedures governing the rescission of primacy are codified at 40 C.F.R. Part 173.

THE ROLE OF TRIBES

Tribes cannot be granted primacy under FIFRA. However, EPA does provide cooperative agreements to tribes who cooperate with EPA for the enforcement of FIFRA and who have developed their own Tribal Codes for pesticide use on tribal lands. See discussion below on cooperative agreements. If a tribal inspector uses tribal credentials for an inspection, enforcement can be pursued by the Tribal Counsel. If EPA credentials are used for an inspection, the inspection file and all information will be forwarded by the tribe to the EPA regional office.

REFERRAL PROCEDURES UNDER FIFRA SECTIONS 26 AND 27

Section 27 of FIFRA requires EPA to refer any information to the states indicating a significant violation of pesticide use laws. In accordance with the Final Interpretive Rule governing FIFRA sections 26 and 27, EPA, in consultation with each state, will identify priority areas, in writing, for formal referral to the state. These priority areas will consist of those pesticide activities in the state that present the greatest potential for harm to health and the environment. The priority areas will be revised on an annual basis based upon the effectiveness of the programs in reduction of the harm associated with pesticide use in the state. This negotiated written agreement between the state and the region will contain the criteria for the selection of significant pesticide use cases.

All pesticide use cases identified as “significant” are referred to the state by EPA in writing and will be formally tracked as set forth in the Final Interpretive Rule. All other use cases will be referred to the state for information purposes and will not be formally tracked. For any “significant” case referred to the state, only state credentials and procedures shall be used and followed. Upon conclusion of a formally referred significant case, the complete original file must be sent to the EPA Regional office.

In determining the adequacy of a state’s enforcement response, the following factors are considered:

(1) Whether the state followed proper sampling and other evidence gathering techniques.

(2) Whether the state responded expeditiously to the referral.

(3) Whether all inculpatory or exculpatory events or information have been documented.

If the state's enforcement response is inadequate and the region is unable to persuade the state to correct any deficiencies through communications with the state, the region may pursue its own enforcement response after notifying the state. That notification should summarize the facts relating to the state inspection, discuss the reasons for EPA's determination that the action is inadequate and state that the EPA will initiate its own enforcement action.

The state has 90 days after the notice to correct any deficiencies. If after that time the Administrator determines that the state program remains inadequate, the Administrator may rescind, in whole or in part, the state's primary enforcement responsibility for pesticide use violations.

Neither sections 26 or 27 of FIFRA limits the authority of the Administrator to enforce the Act where the Administrator determines that emergency conditions exist that require immediate action and the state authority is unwilling or unable to respond to the emergency.

COOPERATIVE ENFORCEMENT AGREEMENTS

While sections 26 and 27 of FIFRA allow EPA to give primary enforcement responsibility to states, it does not extend that authority to tribes. However, section 23 of FIFRA authorizes EPA to enter into cooperative agreements with the states, territories and Indian tribes to delegate the authority to cooperate in the enforcement of FIFRA and to assist in the training and certification of pesticide applicators.

EPA and the states and tribes perform different roles in the cooperative enforcement agreement program. Some areas of responsibility are listed below:

Environmental Protection Agency:

- Provides federal funding to assist the states and tribes through cooperative agreements.
- Provides national focus and program oversight.
- Provides national guidance, compliance/enforcement strategies and policies.
- Provides training for state and tribal inspectors and lab personnel.
- Delegates authority to states and tribes and provides federal credentials for state and tribal inspectors to conduct federal inspections where state or tribal authority is lacking.
- Initiates federal civil and criminal enforcement actions for violations of FIFRA that are referred to EPA by the states or tribes.
- Keeps states and tribes informed of relevant information about pesticide compliance/non-compliance and pesticide use/misuse nationwide

States and tribes:

- Assist with funding for the cooperative enforcement agreement program.
- Participate in the development of national guidance, compliance/enforcement strategies and policies.
- Ensure compliance with both federal and state or tribal pesticide laws by conducting an inspection and sampling program.
- Initiate state or tribal enforcement actions for violations of state or tribal laws.

- Refer fully documented cases of violations of FIFRA to EPA for federal civil or criminal enforcement action.
- Document and refer to EPA potential violations of other federal statutes.
- Keep EPA informed of relevant information about pesticide compliance/non-compliance and pesticide use/misuse within the state or tribal lands.

WHEN TO USE FEDERAL CREDENTIALS/FORMS/SOPS

An inspector must **never** use both state or tribal authority and federal authority for the same inspection.

USING STATE/TRIBAL CREDENTIALS, FORMS AND PROCEDURES

A state inspector must always use state authority, state credentials, state forms and state procedures when conducting inspections where the state has primacy. If the inspector initiates an inspection under state/tribal authority but discovers possible federal, rather than state, violations, the state may refer the federal violations to EPA for further investigation and/or enforcement action. Tribes should use their own credentials when they have authority under their laws and codes to conduct the inspection. Similarly, a tribe may refer any suspected federal violations to EPA for further investigation and/or enforcement action.

USING FEDERAL CREDENTIALS/FORMS/SOPS

The state or tribe must use federal credentials/forms/procedures when conducting inspections that they do not have the authority to conduct under their own state laws or tribal codes or in instances where EPA makes a formal referral to the state or tribe to investigate on behalf of the Agency. Tribes should use federal credentials to inspect where the tribe lacks its own authority or where it lacks authority to monitor and enforce Federal-only requirements. Generally, tribal inspectors will be authorized to conduct inspections on EPA's behalf only within the boundaries of the tribe's Indian Country.

Even with EPA credentials, states are not authorized to conduct inspections on tribal lands unless allowed by a written agreement between the tribe and the state.

When states or tribes with cooperative enforcement agreements use federal credentials, federal inspection forms and federal inspection procedures, the inspector must send the original inspection report and files to the applicable EPA office. The state or tribe may retain a copy of the file, to be used if asked to participate in EPA's enforcement actions. It should be noted that federal law, including FOIA and the requirements pertaining to CBI, apply when states or tribes are conducting any inspection using federal credentials (see Chapter 1).

Section 22(b) of FIFRA directs the Administrator to cooperate with other federal and state agencies in carrying out the provisions of the Act. The objective is to improve management controls and response to pesticide-related cases that are referred between:

- EPA and the Food and Drug Administration (FDA).
- EPA and the United States Department of Agriculture (USDA).
- EPA and United States Customs and Border Protection (CBP)(see Chapter 12).
- EPA and other federal and state agencies.

MEMORANDUM OF UNDERSTANDING

The Memorandum of Understanding (MOU) between FDA, USDA, and EPA on Regulatory Activities Concerning Residues of Drugs, Pesticides and Environmental Contamination in Foods and Imported Pesticides and Devices, provides that:

1. FDA district offices will notify appropriate EPA regional offices when they encounter, through investigation or sample analysis, pesticide residues on foodstuffs that may be the result of the misuse of pesticides. EPA, in turn, will notify FDA whenever pesticide misuse is found which might result in illegal pesticide residues in food.
2. Each agency is to keep the other agency informed of the results of its follow-up and regulatory actions.

PROCEDURES

FDA and USDA Referrals to EPA

Field staff of FDA and USDA will refer cases of suspected pesticide misuse to EPA when:

(1) They are in possession of evidence that clearly demonstrates a pesticide was used on the food, feed, meat or poultry in a manner contrary to its EPA-approved use and labeling.

(2) FDA or USDA laboratory results show residues of a pesticide for which FDA regulatory action would be initiated against the food, feed, meat or poultry because:

- The tolerance for the pesticide is exceeded.
- No tolerance (or exemption from tolerance) has been established or the tolerance has been revoked and the level of residue appears to be due to purposeful use as opposed to environmental or some other unavoidable source of contamination.
- The misuse occurred while the food, feed, meat or poultry was in domestic production, shipment or storage. (Note: Imports found to contain illegal pesticide residues at time of entry are not to be referred to EPA). FDA and USDA retain authority to detain, seize or destroy any illegal or contaminated commodity.

- The person or firm that misused the pesticide is known or suspected.

FDA and USDA also will inform EPA of any other state or local agencies that have been notified.

The EPA response to FDA and USDA illegal residue referrals will normally be a referral to the appropriate state or tribal lead pesticide agency for follow-up. Referrals will be tracked and reported to FDA and USDA in accordance with procedures established by the regions.

EPA Referrals to FDA and USDA

The USDA enforces pesticide tolerances on agricultural products including meat, poultry and some egg products. The FDA enforces pesticide tolerances for all other food products. EPA inspectors may discover potentially illegal pesticide residues on food or agriculture products during FIFRA inspections. When EPA discovers potentially illegal residues, it must refer the matter to the FDA or USDA so the product can be intercepted and tested as necessary. Examples of situations that might result in illegal pesticide residues include accidental pesticide spills, excessive pesticide use in a crop nearing harvest, fruit or grain fumigation over the prescribed rates, pesticide misuse in a food-processing facility or the misuse of pesticides in and around slaughterhouses.

Referrals between EPA and State or Tribal Agencies

EPA may make formal or informal referrals to the states or tribes and vice versa. Referrals should include the following elements whenever possible:

- Cover letter/memo containing:
  - A description of the situation.
  - Requests for specific actions from receiving agency.
  - Recommendations for receiving agency.
  - A description of any enforcement actions planned or taken.
  - A list of important deadlines.
- Complete inspection report (including all attachments and documentation).

INTERAGENCY RESPONSE TO EMERGENCY SITUATIONS

If an inspector encounters an emergency situation, such as pesticide misuse or incidents that may result in harmful human exposure, the inspector should immediately inform an EPA manager and/or supervisor in addition to the inspection target. Emergency situations may require immediate interagency action, and EPA must notify the necessary agencies immediately so that the hazardous situation can be corrected promptly.

EXHIBIT 4-1: INTERAGENCY REFERRAL FORMAT

1. **REFERRAL TO**	**2. REFERRED BY**
Agency: Location:	Agency: Referring Official: Phone Number:
3. DATE REFERRAL FORWARDED	**4. OTHER AGENCIES NOTIFIED**
Date Mailed: Advance Telephone or other electronic Notification Given: • ❒No • ❒Yes Date: To Whom:	Other Agencies Notified and Contact Person in Each:
5. DESCRIPTION OF INCIDENT/REASON FOR REFERRAL	
6. FIRM RESPONSIBLE	**7. FIRM (INDIVIDUAL) AFFECTED**
Name and Location of Firm Responsible for Problem:	Name and Location of Firm or Individual Affected by Problem:
8. DATE REFERRAL RECEIVED	**9. REVIEWING OFFICIAL**
Date of Telephone Notification: Date Received by Mail:	Name/Title of Person Responsible for Determining Response to Referral: Phone Number:
10. FOLLOW-UP DECISION	
❒ Immediate Follow-up ❒ Non-Immediate Follow-up	❒ No Follow-up Reason: Date Follow-up Decision Made:
11. ACTION TAKEN	
Describe follow-up and results.	
12. FEEDBACK REPORT	
Send a copy of completed form to this address at referring agency:	

Referring Agency: Complete Blocks 1-7 and 12.
Receiving Agency: Complete Blocks 8-11, and send to address in Block 12.

CHAPTER FIVE

GAINING ENTRY

CONTENTS

Statutory Inspection Authorities 2
Notice of Inspection versus Consent to Enter 3
Gaining Entry to Private Property 3
Exceptions to the Warrant Requirement 4
Consent 4
Open Fields 4
Exigent Circumstances 4
Plain View 5
Making Sure Consent Is Informed 5
What to Do if Consent to Inspect is Denied 6
Warrant Authority 6
Procedures 7
Obtaining the Warrant 7
Contacting the U.S. Attorney 7
Requirements for Obtaining a Warrant 7
Executing the Warrant 8
Denial of Entry 9
Inspecting with a Warrant 9
Returning the Warrant 10
Challenges to the Warrant 10
Exhibit 5-1: Model Warrant 12
Exhibit 5-2: Model Warrant 14

Gaining Entry

STATUTORY INSPECTION AUTHORITIES

FIFRA section 9(a), 7 U.S.C. §136g(a), provides the authority for an inspector to enter, at reasonable times, any establishment or other place where pesticides or devices are being held for distribution or sale, for the purpose of inspecting and obtaining samples of any pesticides or devices packaged, labeled and released for shipment, and samples of any containers or labeling for such pesticides or devices.

In addition, section 9(a) provides authority to enter, at reasonable times, any place where there is being held any pesticide, the registration of which has been suspended or canceled for the purpose of determining compliance with section 19 of the Act.

FIFRA section 12(a)(2)(B), 7 U.S.C. §136j(a)(2)(B), makes it unlawful for any person to refuse to allow any entry, inspection or sampling authorized by FIFRA.

FIFRA section 8(a), 7 U.S.C. §136f(a), describes the Administrator's authority to prescribe regulations requiring producers, registrants and applicants for registration to maintain records with respect to their operations and the pesticides and devices produced and to make these records available for inspection and copying.

FIFRA section 8(b), 7 U.S.C. §135f(b), requires producers, registrants, applicants for registration, distributors, carriers, dealers or any other person who distributes or sells any pesticide or device subject to FIFRA, to make available for inspection and copying all records showing the delivery, movement or holding of pesticides or devices, including the quantity, the date of shipment and receipt and the name of the consignor and consignee, upon request.

FIFRA section 12(a)(2)(B), 7 U.S.C. §136j(a)(2)(B), makes it unlawful for any person to refuse to prepare, maintain, or submit any records and reports required by or under sections 5, 6, 7, 8, 11 or 19. In addition, this section makes it unlawful for any person to refuse to allow any entry, inspection, copying of records or sampling authorized by FIFRA.

NOTICE OF INSPECTION VERSUS CONSENT TO ENTER

The main function of a Notice of Inspection is to satisfy the requirement in FIFRA Section 8 and 9 to present "a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing". Securing consent to enter private property is a Constitutional requirement and is different from the FIFRA presentation requirement. Consent to enter may be given to the inspector verbally (and noted by the inspector in field notes) or by signing the Notice of Inspection. The absence of a Facility Official's signature on the Notice of Inspection does not invalidate the Notice of Inspection or establish that consent to the inspection was not provided or that the proper procedures were not followed.

GAINING ENTRY TO PRIVATE PROPERTY

To conduct an inspection, the inspector must gain entry to private property. The U.S. Constitution, however, guarantees a reasonable expectation of privacy. Therefore, to gain entry to private property to conduct an inspection, EPA needs to obtain a warrant UNLESS the inspector receives the informed consent from the owner of the property or from a person in control of the property in the absence of the owner. If consent is denied and a warrant is necessary, a warrant can be based on "probable cause" or a "neutral administrative inspection scheme." "Probable cause" is a reasonable suspicion that a violation has occurred. EPA conducts inspections pursuant to a neutral inspection scheme when it is not doing "for cause" inspections. A neutral inspection scheme allows for a non-arbitrary method of identifying inspection targets and the neutral selection of establishments for inspection. A "neutral inspection scheme" as a basis for inspection was developed by the U.S. Supreme Court in *Marshall v. Barlow's Inc*., 436 U.S. 307 (1978).

To conduct an inspection using FIFRA authority, inspectors must present EPA credentials, use EPA forms and EPA procedures. Inspections conducted under state pesticide statutory authorities must follow state authorities, presenting state credentials and using state form(s), and in accordance with established state inspectional protocols. Showing appropriate credentials and providing an adequate Notice of Inspection serve an important function in gaining entry, under these circumstances, and informs the property owner as to the purpose and authority for the inspection.

Unless it is to the advantage of EPA, inspection targets are not notified of a pending FIFRA inspection. It is Agency policy that inspections conducted under FIFRA are unannounced inspections. EPA conducts unannounced inspections, with no prior contact with the establishment, company or any individual prior to the arrival of the inspector at the location.

EXCEPTIONS TO THE WARRANT REQUIREMENT

CONSENT

An inspector can enter private property to conduct inspections by obtaining valid consent. For the consent to be valid, it must be freely and voluntarily given and not given because of duress, misrepresentation or coercion (either expressed or implied). While the law does not require that a subject be advised of his/her right to refuse to give consent, if the inspector believes such knowledge may be helpful in validating the consent and in overcoming any taint of implied coercion, he/she may inform the consenting party of his/her right to refuse voluntary entry. In addition, the person granting the consent must be authorized to do so. The inspector must be certain that the consenting party is the owner or has the premises under his/her control and has at least the apparent authority to give consent.

If a FIFRA inspector plans to make multiple visits to the same location for inspection or sampling purposes, the inspector must gain consent for each entry unless the inspector obtained prior consent to cover all necessary entries. Accordingly, at the onset of an inspection, the inspector must seek to gain consent sufficient to authorize all entry and sampling activities he/she contemplates will be necessary to complete the inspection.

OPEN FIELDS

“Open fields” are areas where a landowner normally does not have a reasonable expectation of privacy. While the preferred procedure is to obtain valid consent prior to entry, the courts have established that inspectors may enter open, private lands in the official performance of their duties. The inspector may technically be a trespasser on private property, but this fact will not prevent the lawful use of any evidence obtained in these open fields. This inspection authority does not extend to a residence or the area immediately surrounding a residence.

EXIGENT CIRCUMSTANCES

The law does not require a public official to stand by helplessly while a serious offense endangering human health or the public safety is occurring on private property. If there is insufficient time to procure a warrant before serious harm will occur and if consent to enter cannot be readily obtained, an inspector may enter the property to assist in preventing imminent harm to human life. Because of the heavy burden imposed on the Agency to show that its entry without authority was justified, this doctrine shall be used only in rare and emergency circumstances.

PLAIN VIEW

There is no reasonable expectation of privacy concerning things in "plain view." The plain view doctrine is an acknowledgment by the courts that an inspector lawfully engaged in the course of his/her duties is not required to wear blinders or close his/her eyes to whatever is occurring around him/her. This principle applies regardless of the nature of the inspection (use, producer, marketplace, etc.). The following elements are required for a plain view observation:

- **Lawfully present**—The inspector must be justified in being where he/she is at the time the plain view observation is made. Lawful presence may be gained through such avenues as statutory authority, a valid search warrant, consent or "open fields."
- **Inadvertent discovery**—The inspector must discover the evidentiary items accidentally. The plain view doctrine will not apply if the inspector has probable cause to believe that an item is on certain premises and goes on those premises with the intention of searching for that item; such a discovery is not inadvertent.
- **Apparently incriminating nature**—The inspector must have reasonable grounds to believe immediately, without further investigation, that the item in plain view constitutes evidence of a violation of the law.

MAKING SURE CONSENT IS INFORMED

Both sections 8 and 9 of FIFRA require that the inspector present to the owner, operator or agent in charge, appropriate credentials and a written statement (Notice of Inspection) as to the reason for the inspection and a statement as to whether the inspector suspects a FIFRA violation. If no violation is suspected, the inspector should mark that the inspection is a "neutral inspection scheme" on the Notice of Inspection form. However, if the inspector suspects a violation, the inspector must mark that the inspection is "for cause" and clearly state the suspected violation (i.e. suspected unregistered pesticides in violation of FIFRA) on the Notice of Inspection form. The inspector must fill out the Notice of Inspection form properly and completely. If the inspector is unsure whether the inspection is "for cause" or a "neutral inspection scheme" the inspector should contact his or her supervisor before attempting to gain entry.

Upon arrival at the establishment, the inspector must:

1. Identify and introduce himself/herself to the owner, operator, or agent in charge of the establishment (responsible official of the facility), in a professional manner.
2. Present EPA credentials. Do not relinquish possession of the credential and do not allow anyone to make copies of the credential. As noted above, for FIFRA inspections, the

inspector must present only EPA credentials. Do not present both EPA and state credentials during entry.

3. Request to discuss the purpose of the inspection with the owner, operator or agent in charge and any other responsible official(s) of the facility.
4. Issue the owner, operator, or agent in charge a completed Notice of Inspection (EPA Form 3540-2) (Exhibit 1-1), which contains the reason for the inspection and whether the inspection is "neutral scheme inspection" or "for cause" (including any suspected violations). As stated above, the absence of a Facility Official's signature will not invalidate the Notice of Inspection, or establish that consent to the inspection was not provided or that proper procedures were not followed.

These entry procedures are critical to ensure that an inspection is conducted legally, with the informed consent of the responsible official of the establishment and that any evidence gathered during the inspection can be used in an enforcement proceeding.

WHAT TO DO IF CONSENT TO INSPECT IS DENIED

The inspector must explain the authority to conduct inspections under sections 8 and 9 of FIFRA and that not permitting the inspection would constitute a violation of section 12(a)(2)(B)(iii). If consent to conduct and complete the inspection is still denied, the inspector must leave the facility and immediately call his/her supervisor and provide information on the denial of entry. The supervisor and/or an EPA attorney may negotiate entry or EPA may seek a warrant to continue the inspection.

WARRANT AUTHORITY

If consent is denied, a warrant can be sought based on "probable cause" or a "neutral administrative inspection scheme". "Probable cause" is a reasonable suspicion that a violation has occurred. EPA conducts inspections pursuant to a neutral inspection scheme when it is not doing "for cause" inspections. A neutral inspection scheme allows for a non-arbitrary method of identifying inspection targets and the neutral selection of establishments for inspection. See, "The Conduct of Inspections after the Barlow's Decision" (GM-5) cited at the beginning of this Chapter. Under FIFRA section 9(b), officers or employees, duly designated by the Administrator, may obtain and execute warrants authorizing the following:

- Entry for the purposes of sections 8 and 9.
- Inspection and reproduction of all records showing the quantity, date of shipment, and names of the consignor and consignee of any pesticide or device found in violation of FIFRA at any establishment and, in the event of the inability of any person to produce

records containing such information, all other records and information relating to such delivery, movement or holding of the pesticide or device.

- Seizure of any pesticide or device that is in violation of FIFRA.

To support the request for a warrant, the inspector must prepare detailed notes giving the name of the person approached, his/her title, time of denial, reason for denial (if given) and reason for inspection (i.e., "probable cause" or "neutral inspection scheme"). This information is essential to ensuring a warrant is obtained.

Note that refusal of entry is not necessarily a prerequisite to obtaining a warrant. EPA may obtain a pre-inspection warrant where the company has a history of prior refusal, or the distance to a U.S. attorney or a magistrate is so considerable that excessive travel time would be required if entry were denied.

PROCEDURES

OBTAINING THE WARRANT

The inspector plays a significant role in seeking a warrant. His/her knowledge and experience relating to the denial of entry are crucial to the drafting of warrant documents. The inspector is responsible for: (1) obtaining information that specifically describes the premises to be searched; (2) providing specific information with regard to the reason(s) for the inspection, including the items to be inspected; and (3) helping to determine which laws apply or may have been violated.

Drafting warrant documents is a particularly important area where attorneys and inspectors must work as a team.

CONTACTING THE U.S. ATTORNEY

To obtain a search warrant, EPA must contact the U.S. Attorney's Office in the district in which the property is located and assist the assigned Assistant U.S. Attorney in preparing the warrant and any necessary affidavits.

REQUIREMENTS FOR OBTAINING A WARRANT

When seeking a warrant, three documents must be prepared: (1) an application for a warrant;

(2) one or more affidavits in support of the warrant; and (3) the warrant itself. Each document must contain a caption with the district court of jurisdiction, the title of the action, and the title of the particular document. Exhibit 2-1 is an example of an affidavit to support an application

for a warrant. Exhibit 2-2 is an example of a warrant that may be prepared for the magistrate's signature.

The application for a warrant must identify the statute (FIFRA) and regulations under which the Agency is seeking the warrant and identify clearly the site or establishment to be inspected (including, if possible, the owner and/or operator of the site). The U.S. Attorney or Assistant U.S. Attorney must sign the application.

The affidavits in support of the warrant application are crucial. Each affidavit must consist of consecutively numbered paragraphs describing all of the facts that support the issuance of the warrant (probable cause). If there is no probable cause, the warrant must recite or incorporate by reference the neutral administrative scheme that is the basis for inspecting the particular establishment. Someone with personal knowledge of all the facts stated must sign each affidavit, although that person can rely upon "hearsay" or secondhand knowledge - this person would most likely be the inspector who has been denied entry. Note that an affidavit is a sworn statement that must either be notarized or personally sworn to before the magistrate.

The warrant itself is a direction to an appropriate official (an EPA inspector, law enforcement personnel or other federal officer) to enter a specifically described location and perform specifically described inspection functions. Because the inspection is limited by the terms of the warrant, it is important to specify to the broadest extent possible the areas that are intended to be inspected, any records to be inspected, any sample to be taken, any articles to be seized, etc. Note, however, that a vague or overly broad warrant will probably not be signed by the magistrate and may prove susceptible to constitutional challenge.

The warrant must be ready for the magistrate's signature at the time of submission. Once the magistrate signs the draft warrant, it is an enforceable document.

Either following the magistrate's signature or on a separate page, the draft warrant must contain a "return," which is used to report that the warrant was executed. The return is to be signed and dated by the inspector after completing the inspection (see "Returning the Warrant" below).

EXECUTING THE WARRANT

Once a judge or magistrate signs the warrant, the inspector may execute the warrant. Warrants are executed only by a physical entry onto the premises and must be executed without undue delay. The warrant will usually direct that it be executed during daylight hours and specify the date by which it must be executed. It is customary to show the property owner a copy of the warrant or provide a copy. If more than one person will be conducting the inspection, it is important that the inspection team members determine each member's role (i.e., who is going to do what and when) before going to the facility.

DENIAL OF ENTRY

Where there is high probability that EPA will be refused entry, even with a warrant, or there exists a likelihood of threats of violence, the inspector must be accompanied by a U. S. Marshal, county sheriff, state or local police officer when executing the warrant. For reasons of personal safety, the inspector must not attempt forcible entry of the facility at his/her own initiative.

If the facility representative refuses entry to an inspector holding a warrant but not accompanied by a law enforcement officer, the inspector must leave and so inform the Assistant U. S. Attorney and the designated EPA attorney. They will take appropriate action, such as: (1) sending the inspector back to the facility, accompanied by law enforcement personnel or (2) seeking a citation for contempt.

Where law enforcement personnel accompany the inspector, the law enforcement officer will execute the warrant. If a refusal or threat to refuse occurs, the inspector must abide by the law enforcement officer's decision whether to leave, seek forcible entry or take other action.

INSPECTING WITH A WARRANT

Except as described below, the inspector must conduct the inspection strictly in accordance with the warrant. If the warrant authorizes sampling, the inspector must be sure to follow all procedures carefully, including the presentation of receipts for all samples taken (see Chapter 17 for product sampling procedures). If the warrant authorizes EPA to take records or other property, the inspector must provide a receipt for the property taken and maintain an inventory. The judge or magistrate will examine the inventory as part of the warrant return to ensure that the inspector did not exceed the warrant's authority and will become an exhibit to the original warrant when returned to the court.

Inspectors must keep the following points in mind when conducting an inspection pursuant to a warrant:

- Inspectors should only collect evidence within the scope of the warrant.
- Be aware of other possible evidence of wrongdoing. Such evidence generally is obtainable as long as the inspector has the lawful authority to be where he/she is and the evidence is in "plain view" (as described in this Chapter).
- The warrant will specify whether the inspector needs to split samples and how to handle certain documents on site (i.e., whether documents may be removed or copied and removed). If, for some reason, document removal is not possible or authorized in the warrant, arrange for the documents to be copied, scanned or photographed on site. If the inspector anticipates a large number of records, EPA recommends the use of a

portable scanner or laptop, or, if not available, the inspector can dictate the contents of the documents into a recording device.

- As with all inspections, interview as many individuals as possible. There are no restrictions on asking questions, although there is no obligation for the facility's representatives or employees to respond.
- If the inspector believes that the facility may have intentionally destroyed records, the inspector should make observational notes in his/her field notebook and inspection report and contact his/her supervisor as soon as possible. EPA's criminal enforcement division may need to be notified if intentional record destruction is observed.

RETURNING THE WARRANT

A warrant is "returned" when EPA submits a written report to the court describing when and where the warrant was executed, who executed the warrant, an inventory of the records or samples collected and, if a copy of the warrant was given to someone, the return must list that person's name and address. The inspector must work as a team with the EPA attorney to provide the information necessary to return the warrant within the time restriction required by the court. Failure to return the warrant in a timely manner could result in contempt action against the executing officials. The person who executes the warrant (i.e., the person who performs the inspection) must sign the return form and give it and the warrant to the U.S. Attorney, who will formally file the documents with the court.

CHALLENGES TO THE WARRANT

The possibility always exists that a facility representative will challenge a warrant and the evidence obtained. The warrant and all evidence gathered pursuant to it, or portions of evidence obtained in an otherwise valid warrant, can be overturned by the court. Some of the typical bases for challenges to a warrant or evidence (whether or not they are successful) include the following:

- Insufficient cause for issuance of the warrant.
- Insufficient statement or affidavit supporting the warrant.
- Inaccurate information in the supporting statement or affidavit.
- Insufficient description of the premises or items to be seized.
- Searches beyond the scope of the warrant.
- Failure to follow appropriate procedures for serving or returning the warrant.

To avoid challenges relating to EPA's authority under a warrant, all FIFRA inspectors should follow the procedures provided above for obtaining, executing, and returning a warrant.

United States District Court

For the_____District of _____

In the Matter of the Search of: Docket No.

(Briefly describe the property to be searched Case No.

or identify the business by name and address)

AFFIDAVIT IN SUPPORT OF APPLICATION FOR A WARRANT

_____*(your name)* _____, being duly sworn upon his oath, according to law, deposes and says:

1. I am duly authorized *(title)*_ of the *(division)*, United States Environmental Protection Agency, Region____. I hereby apply for a warrant pursuant to Section 9 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. Section 136 *et seq*., for the inspection and/or sampling of the items named below in the possession, custody or control of the *(name of company or owner)*.
2. This warrant in sought under Section 9 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, (7 U.S.C. Section 136g), which provides:

"(b) WARRANTS - For purposes of enforcing the provisions of this Act and upon a showing to an officer of court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing –

"(1) entry for the purpose of this section;

"(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this Act and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device; and

3. *(Name of establishment, person, or place)* is a *(describe its business)* that the undersigned compliance officer of the United States Environmental Protection Agency has reason to believe is in violation of the Federal Insecticide, Fungicide and Rodenticide Act, as amended. This belief is

based upon the following facts and information: *(summarize the reasons why a violation is suspected and the facts justifying the suspicions)*.

4. The *(inspection, reproduction of records, sampling, issuance of the stop sale, use or removal order)* will be carried out with reasonable promptness, and a copy of the results of analyses performed on any samples or material collected will be furnished to the owner or operator of the subject establishment or property.
5. The compliance officer may be accompanied by one or more other compliance officers of the United States Environmental Protection Agency.
6. The undersigned compliance officer requests immediate entry to *(Name of establishment or place)* to perform the inspection, reproduction of records, sampling, or the issuance of a stop sale, use or removal order [optional, if necessary].
7. A return will be made to the court at the completion of the inspection, reproduction of records, sampling or issuance of a stop sale, use or removal order.
8. The authority of the issuance of the inspection warrant is Section 9 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and *Camara v. Municipal Court of the City and County of San Francisco*, 387 U.S. 523 (1967), *See v. City of Seattle*, 387 U.S. 541 (1967), and *Marshall v. Barlow's Inc*., 436 U.S. 307 (1978).

_____
Applicant's signature

_____
Printed name and title

Sworn before and signed in the presence of _____
Notary public's signature

_____
Printed name

My Commission expires on _____

EXHIBIT 5-2: MODEL WARRANT

United States District Court

For the_____District of _____

In the Matter of the Search of:
(Briefly describe the property to be searched or identify the business by name and address)

Docket No.
Case No.

Warrant for Inspection, Reproduction of Records, Sampling, and Issuing Stop Sale, Use or Removal Order of Pesticides or Devices Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, (7 U.S.C. Section 136).

To ___(Name)___, ___(Title)___, ___(Division)___, Environmental Protection Agency, Region ___, and any other duly authorized enforcement officer of said division:

Application having been made and probable cause shown, by *(Name of Officer)*, for inspection and sampling of packaged, labeled and released pesticides or devices, as well as labeling and containers found in the establishment described below; and for inspection and reproduction of records showing quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in said establishment which is adulterated, misbranded, not registered in the case of a pesticide or otherwise in violation of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, or should such records not be available for inspection, all other available records and information relating to such delivery, movement, or holding of any pesticide or device which is in violation of the said Act; for the issuance or surveillance of any stop sale, use or removal order of any pesticide or device which is in violation of the said Act; all within the establishment or place described as:

_____
Name of establishment or place

_____
Address

_____
City, State and Zip Code

-or-

Application having being made and probable cause shown, by (Name of Officer), for inspection or sampling of pesticide used in violation of the said Act, at the place described as:

_____
Name of establishment or place

_____
Address

_____
City, State and Zip Code

Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, the federal regulations promulgated thereunder, and the decisions of Camara v. Municipal Court of the City and County of San Francisco, 387 U.S. 523 (1967), See v. City of Seattle, 387 U.S. 541 (1967), and Marshall v. Barlow's Inc., 436 U.S. 307 (1978) you are authorized to enter (immediately) the above described premises upon presenting this warrant and therein carry out the inspections, sampling, reproduction of records, and/or issuance or surveillance of any stop sale, use of removal order described above.

Date and time issued: _____ _____
Signature of Magistrate

Return of Service

I hereby certify that a copy of the within warrant was served by presenting a copy of the same to *(facility owner of agent)* on *(date)* at *(location of establishment or place)*.

_____
Signature of person making service

_____
Printed name and title

Return

Inspection of the establishment described in this warrant was completed on *(date)*.

_____
Signature of person conducting inspection

_____
Printed name and title

CHAPTER SIX
PESTICIDE PRODUCT SAMPLING

CONTENTS

Statutory Authority 3
Objectives 3
Policy 3
Types of Samples 4
Sample Procedures 5
- Numbering of Samples (whether physical or documentary) 6
- Duplicate Samples 6
- Small-Sized Units 7
- Larger-Sized Units 8
- Dry Material 8
- Liquid Material 8
- Gas or Fumigants 9
- Labels 9
- Samples Via Internet Purchase 9

After Sampling 10
- Restoring Lot to Order 10
- Preparing the Receipt for Samples 10
- Payment for Samples 11

Sample Documentation 11
- Responsibility 11
- Records Showing Shipment 12
  - Invoice 13
  - Bill of Lading 13
  - Freight Bill 13
  - Waybill 14
  - Mail or Parcel Service Shipments 14
  - Shipments by Noncommercial Vehicle 14

Statement 15
Sample Preparation, Custody and Handling 15
Identification of Samples and Labels 15
Identification of Documents 16
Records 16
Accompanying Literature, Labeling, Photographs and Exhibits 16
Sample Custody and Integrity 16
The EPA Official Sample Seal and Polybagging 16
Sample Integrity and Transfer 17
Mode of Transfer 18
Hand Delivery 18
Common Carrier 18
U.S. Postal Service 19
Exhibit 6-1: Examples of Records 20

PESTICIDE PRODUCT SAMPLING

STATUTORY AUTHORITY

FIFRA section 9(a) authorizes any officer or employee duly designated by the Administrator to enter, at a reasonable time, any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices packaged, labeled and released for shipment and samples of any containers or labeling for such pesticides or devices. This includes the sampling of pesticides and devices that have been produced by the establishment within the past two years and exist elsewhere in the channels of trade.

FIFRA section 9 requires the inspector to offer the establishment representative duplicate samples of physical samples collected during the inspection.

FIFRA section 12(a)(2)(B) makes it unlawful for any person to refuse to allow a "duly designated agent of the EPA Administrator" to take a sample of any pesticide pursuant to FIFRA section 9.

OBJECTIVES

An official sample of a pesticide formulation or device is necessary for use as evidence in many of the enforcement actions taken resulting from a producer, marketplace or dealer inspection. A sample must be suitable to support an allegation that a violation has occurred. Therefore, the sample must conform to the rules regarding admissibility of evidence; specifically, the inspector must establish the chain of custody for the sample(s), where the sample has been and how it was treated once it was collected. A properly collected, prepared and documented sample includes the following:

- A sufficient portion of a batch of a pesticide for laboratory analysis.
- Photographs and copies of records, data or correspondence.
- Labeling and/or literature, or copies of these items, pertaining to the sampled product and/or batch.
- Signed statements from persons who may potentially serve as witnesses.
- Properly filled out chain-of-custody forms

POLICY

Use the procedures outlined in this chapter to collect and prepare samples. The inspector should fully document any deviations from these procedures in his or her field notebook.

Deviations from the procedures in this manual may be very important to the laboratory when analyzing the samples.

Promptly deliver or forward samples and records to the laboratory. Do not hold pesticide formulation samples for more than five working days from the time of collection to the time of shipment to the laboratory.

There are four main potential sources of pesticide product samples: (1) inspections of pesticide producing and device producing establishments (see Chapter 9); (2) marketplace inspections (see Chapter 9); (3) use inspections (see Chapter 8) and (4) import inspections (see Chapter 12). Obtain lists from your EPA regional office of pesticides or devices produced at various establishments. Unregistered pesticides, investigational samples or pesticides or devices that are not available at a producer's establishment may be available for sampling at a marketplace, such as wholesale and retail establishments, farm dealerships, seed, feed and fertilizer outlets and many home improvement stores.

TYPES OF SAMPLES

Official samples may be used as part of legal or regulatory actions. There are four types of official pesticide product samples - physical, induced, documentary and import.

- **Physical samples** are actual samples of the pesticide formulation or device. The physical sample may include the original labeled packaging, copies of or photographs of the label and all other labeling associated with the pesticide or device. Collect copies of any records showing the distribution or sale of the physical sample for documentary purposes. Shipping records, bills of lading, waybills, etc., are important because they can substantiate the distribution or sale of the pesticide product or device and are vital to all enforcement cases. A sample usually consists of the entire container of the pesticide or device. When large containers are involved or when small amounts of a pesticide are necessary for analyses, the inspector may choose to subsample the pesticide. This type of sample consists of a portion of the pesticide removed from the original container and placed in a sample container and identified properly. In addition, the label and any additional labeling and/or collateral literature and/or photographs must be documented and identified with the same number as the subsample container. The official sample consists of the physical subsample and the label/labeling and is counted as one sample. If a subsample is collected, the original container that the sample was collected from should be properly re-sealed and identified (i.e., "4 oz. removed on 01/01/2012 by EPA for sampling purpose," inspector's initials).
- **Induced samples (IND)** of pesticides or devices are physical samples that are obtained by mail, telephone, or the internet. Complete documentation is necessary, including the original advertisement. A webpage printout may be advertising of the pesticide product, but consult your supervisor before collecting this evidence

- **Documentary samples (DOC)** are official samples collected in lieu of or in addition to taking physical samples. Documentary samples may suffice when the chemistry of a pesticide is not suspect. Inspectors have some flexibility when collecting documentary samples, but should strive to collect the best evidence. In order of preference, documentary samples may consist of:
    - Photographs of the entire label of the actual container observed by the inspector at the time of inspection. Photograph all sides, including the top and bottom, and photograph the entire product as observed in its retail or warehouse location.
    - For products that may have already been produced and are not on hand, authenticate bin labels or specimen labels by having the owner/operator identify them as identical to the labels on product already sold/distributed and covered by invoices and shipping records obtained during the inspection. Further, establish authentication by obtaining a written notation on the reverse side of the label/labeling, as well as a written statement by the owner/operator, that labels obtained during the inspection are identical to the labels on the products sold/distributed.
    - Specimen labels or other labels obtained by the inspector from sources other than at the establishment or place where the pesticide was observed. The more removed a specimen or other label is from the actual label observed, the greater the effort must be to authenticate the label. These labels must be authenticated by the agent-in-charge, suspect or witness in an official statement on the Receipt for Samples and/or Statement Forms, as identical to the original label observed by the inspector.
- **Import samples (IMP)** are physical or documentary samples of pesticide formulations or devices imported into the United States from foreign countries. Documentation for imported shipments should include U.S. Customs and Border Protection (CBP) entry papers, foreign invoices, shippers' bills of lading, and records showing movement from the port of entry. See Chapter 12, "Pesticide/Device Import and Export Inspections."

SAMPLE PROCEDURES

Inspectors should ensure that sufficient sampling equipment is on hand prior to conducting the inspection. For a listing of suggested equipment, see Chapter 7, "Residue and Environmental Sampling." Immediately following the collection of a sample, the sample should be: (1) officially sealed; (2) labeled; and (3) documented in inspection notes and inspection forms. Collect official pesticide formulation and/or documentary samples from material that is packaged, labeled and deemed released for shipment by the manufacturer or, in the case of producing establishments, has been introduced into the channels of trade in the past two years. The term "packaged, labeled and released for shipment" refers to the point in the production and marketing of a pesticide/device where (1) the product has been produced and (2) has been

introduced into the channels of trade or it is the intent of the producer that such product be introduced into the channels of trade.

At the producer establishment, document intent to introduce the product into the channels of trade by (1) the producer's assertion that the material being sampled is representative of what is actually sold in the marketplace or (2) storage of the product in a loading dock, warehouse or other area where finished goods are held before sale or distribution.

If an inspector can determine that a product is at a distributor or in a wholesale or retail marketplace, that product has been "released for shipment" by the producing establishment and therefore subject to inspection and sampling.

NUMBERING OF SAMPLES (WHETHER PHYSICAL OR DOCUMENTARY)

Every sample requires an identifying number. An example of a sample number consists of: (1) the date (mmddyy); (2) the inspector's credential number (3) an inspection sample sequence number including subsample numbering (A, B, C, or 001, 002, 003); and (4) the inspector's initials.

For example, 01/09/2012-17942-123-001-MP

- 01/09/2012 = date
- 17942 = inspector credential number
- 123 = inspection sequence number
- 001 = sample or subsample number
- MP = inspector initials

DUPLICATE SAMPLES

The inspector should inquire whether the facility would like duplicate samples. If the inspected facility requests duplicate samples, they should be collected, identified, labeled and officially sealed in the same manner as the inspector's official samples. In the case of a larger sized unit, EPA defines a duplicate sample as an equal amount of the product taken in the same manner from the same container. In the case of small-sized units, a duplicate sample is the same number of units taken from the same shipping containers and bearing the same batch or code numbers, if coded.

Small-sized units should not be subdivided for the following reasons: (1) the integrity of the sample is easier to maintain and defend; (2) contamination during sampling is minimized; (3) the possibility of exposure to the inspector and personnel of the firm is diminished; and (4) the laboratory can conduct a net content check on the unit collected, if necessary.

SMALL-SIZED UNITS

Small-sized units are units intended for retail distribution, containing liquids of one gallon or less or solids weighing 20 pounds or less. Take samples from original, previously unopened shipping cases. If more than one batch or lot number is present, take samples from the predominant code or batch. If it is necessary to sample more than one batch or lot, write all lot and batch numbers on the Receipt for Samples to identify the lots or batches. If the labels are not identical, sample all sizes and submit different sizes under separate sample numbers. In addition, record the number of cases of each size. When only a case code is evident, identify the case code. If different sized containers are present and the labels are identical, except for net contents, sample only one size and record the number of cases of each size in the inspection report. Describe all non-sampled lot numbers in the inspection report.

Table 6-1 provides guidance on the number of units that should be collected. However, the inspector may need to consult with the laboratory to determine the amount of pesticide required for analysis.

TABLE 6-1 - SAMPLE SIZES TO COLLECT FOR PESTICIDE PRODUCTS

Product Type	Quantity to Collect
Small-Size Units (liquids and solids)	
Active Ingredients more than 1%	Collect enough units to total at least 10 oz.
Active Ingredients less than 1%	Collect enough units to total at least 10 oz.
Pressurized containers	Collect at least three units
Larger Size Units (Liquids and Solids)	
Active ingredients less than 10%	Collect at least 10 oz. from each of two containers*
Active ingredients more than 10%	Collect at least 10 oz. from each of two containers*
Tank Mixes	Collect at least one 10 oz. sample in addition to a 10 oz. sample of the formulation (refrigerate immediately)

* Sample each container in duplicate if any non-uniformity is evident (i.e., layering, sediment, gross particle-size differences or color non-uniformity.)

* For antimicrobial pesticides, please contact the laboratory for volumes necessary for testing.

LARGER-SIZED UNITS

Larger-sized units (also known as “bulk” units) are those units that contain more than one gallon of liquid or weigh more than 20 pounds of solid material and are for commercial use. Because of the size of these units, inspectors should take a sample of contents of the unit. Depending on the size of the bulk unit, the inspector can take a sample of liquid material by pouring it into a sample container or by withdrawing a sample from the exit valve or other existing opening in the bulk unit. When taking a sample from an exit valve, the inspector may need to let the product flow for a short time before taking the sample. When sampling granular or powder product from bulk units, the inspector may draw the sample by using an available pull-out sleeve at the top of the bag or, where there is no existing opening in the bag, use a sharp object (i.e., knife) to create an opening. When creating an opening, the inspector should be cautious not to make a hole larger than necessary to accommodate the sampling equipment.

Special situations may warrant deviations from these guidelines. If so, the inspector should take the entire large-size unit as the sample and submit it to the laboratory.

DRY MATERIAL

A previously unused, disposable plastic tube available from golf equipment suppliers or home supply stores or a clean grain trier should be used for each batch or lot sampled to avoid any possibility of contamination. Clean glass and metal containers and sampling equipment with a proper solvent (hexane, alcohol, etc.) and air-dry prior to placing the sample into the container.

Clean the tube or trier with a proper solvent and insert it diagonally into the bag through the seam or the “dog ear” to obtain a representative sample of the material from different sections of the bag. Use properly cleaned glass or metal (paint type) containers to contain the sample. Use either a non-stick or polyethylene-lined lid in conjunction with the glass containers for formulation samples. Properly dispose of the tube and other contaminated sampling material. Thoroughly clean the trier with soap and water or solvent and dry before each use or reuse.

See Table 6-1 for recommended sample sizes to collect; consult with the laboratory if you are unsure.

LIQUID MATERIAL

A previously unused, disposable plastic tube, clean glass trier or siphon should be used for each batch or lot sampled to avoid any possibility of contamination.

Inspectors should take a representative sample of liquid material. If the label states to thoroughly agitate the material prior to use, agitate by rolling and shaking the can, barrel, or drum before sampling, if possible. Use glass bottles as sample containers. Either non-stick or polyethylene-lined lids are satisfactory for liquid formulation samples. Do not use rubber or paper-lined lids. Properly dispose of the tubing and other contaminated sampling material.

Consult with your sample analysis laboratory if you are unsure of the amount of product to sample.

A vaccutaner with siphon tube, which has a vacuum in the tube, usually used for blood sampling, can be used in some cases to sample liquid material in large containers. It is relatively easy to use and does not have a large amount of waste to be disposed of, other than the tube and sample needle that is used to puncture the end of the vaccutaner. These devices may be purchased from hospital supply stores and are an inexpensive method of sample collection. Decreased exposure to the inspector from the pesticide itself may be an additional advantage to using this type of sampling container.

GAS OR FUMIGANTS

The inspector should NEVER attempt to take a physical sample of a gas or fumigant product. Instead of a physical sample, the inspector should conduct an inspection of the container and obtain a photograph of the container and the label. If efficacy or formulation data is required for a gas or fumigant product, request that information during the inspection or through an information request letter.

LABELS

A duplicate label, copy or photograph of the label must accompany each physical sample. **Do not remove the container labeling**, because this will cause the pesticide to be misbranded. Bin labels may be used for this purpose. The inspector must make a word-for-word comparison of this label with the labeling on the container sampled to ensure that they are identical. If bin labels are not available, fully legible photographs of all portions of the label are necessary. Another photograph of the entire container, showing the position of the label on the container, should also be obtained. Instant processing, 35mm, or digital cameras may provide the word-for-word substitute for a label, if the camera can zoom in on the label language.

An inspector should be careful to view the digital photo, if possible, to see if the image is sharp enough to obtain the word-for-word comparison of specimen and actual product labeling.

SAMPLES VIA INTERNET PURCHASE

An inspector may find potentially violative pesticides or devices online, through web searches and/or tips and complaints. To sample a product from the internet, the inspector may purchase the product and have it delivered to him/her. When collecting an internet sample, the following protocol may be helpful to ensure sample integrity and provide adequate documentation of the sampling process used:

- Use an EPA Purchase Card or other secure means of purchasing the product.

- Plan for the delivery point (NOT the EPA office building or address site); this could be a mail box, post office box location or other established location where U.S. Mail, or commercial deliveries can be made.
- Document sample integrity and establish chain-of-custody by documenting in the case file:
    - The product purchase order and record of payment;
    - The receipt of the product at the specified delivery location or the tracking number and record of delivery by U.S. Mail or commercial carrier;
    - The inspector's observations of the package and photos of all sides of the shipping container prior to opening;
    - Photos of the open package to document the package, packing material, container etc.; and
    - Photos of the actual product ordered (including the full label and container) and any labeling that accompanied the product.
- As with any sample obtained, identify an internet sample using the sample identification protocol described in this Chapter. Chain of Custody begins after the integrity of the sample (official identification and sealing) has been established by EPA.
- If sending the product for testing and analysis, determine if chemistry and/or efficacy testing/analysis are necessary. Then ship the sample to the EPA laboratory for analysis and include the Chain-of-Custody Record Form (EPA Form 3540- 41, see Exhibit 1-1). Ship the sample following DOT and/or commercial carrier shipping procedures for pesticides and keep all documents relating to the chain of custody in the case file.

AFTER SAMPLING

RESTORING LOT TO ORDER

The inspector should attempt to restore a sampled lot on the premises to an orderly condition. Clean up spillage. Close containers. Return hand trucks, tools, rags, glue pots and other supplies or equipment to their proper pre-sampling position. Some facilities will restore lots to order after inspectors sample and may instruct an inspector to allow them to restore the area to its pre-sampling condition.

PREPARING THE RECEIPT FOR SAMPLES

Issue a Receipt for Samples (EPA Form 3540-3; see Exhibit 1-1) for all samples collected. Identify each sample on the Receipt for Samples with the name of the product, EPA Registration

Number, batch/lot number, other identifying product information and sample identification number. The inspector and the owner, operator or agent in charge of the establishment should sign the Receipt for Samples.

The preparation of the Receipt for Samples should be self-explanatory. It is the inspector's responsibility that the facility representative understands that by signing the Receipt, he/she is acknowledging the fact that the physical and documentary samples were obtained from products that were packaged, labeled and released for shipment or, having been shipped, were being held for distribution or sale. Provide the establishment copy of the Receipt for Samples to the facility and retain the inspector's copy. In addition, make a copy of the Receipt for Samples Form and include it with any samples sent to a laboratory.

PAYMENT FOR SAMPLES

FIFRA requires that EPA be allowed to inspect and sample but it is silent on the need to compensate. Distributors and dealers can be offered invoice costs plus a nominal charge (usually 10 to 15%) for freight, handling and storage. Producers can be offered their production cost.

SAMPLE DOCUMENTATION

RESPONSIBILITY

Document samples in accordance with this section. Ensure that the records obtained are those covering the specific pesticide product(s) or device(s) sampled.

Do not remove the firm's only copy of any record. If duplicates are not available, photocopy, photograph or hand copy all necessary records. Examine all copies to ensure that they clearly contain all relevant markings that appear on the original. Hand copies of records on EPA forms must be accurate and legible.

Identify all copies (this includes the firm's original copies) with the inspection sample sequence number (any sample or sub-sample number), the date (mm/dd/yyyy), and the inspector's initials (i.e., Sample number-Date -Credential number-Initials). The inspector should mark "EPA," the date and his or her initials in an inconspicuous manner on the reverse side of the original records from which copies were made. If the firm's record has information on both sides, the inspector's identification should appear inconspicuously in a clear space and be circled. These procedures will ensure positive identification of the document copies in question.

For distributor-level suspected violations, the inspector should document the handling and storage of the sampled product and establish the source and distribution for any accompanying literature and or labeling.

See Exhibit 6-1 for types of records that may be collected as documentary evidence relating to a sample.

RECORDS SHOWING SHIPMENT

Collecting records that document the movement of pesticides or devices in the channels of trade is an integral part of sample collection. These records indicate the responsible party in misbranding and/or adulteration cases and are key to shifting primary responsibility away from the retailers. In addition, these records are vital in determining an appropriate penalty since each shipment or sale is a separate violation of FIFRA. When there are suspected FIFRA violations, inspectors should attempt to document sufficient evidence of separate shipments/sales or collect records documenting separate days of shipments or sales. Obtain invoices, transportation, shipping and/or purchase records for each official sample of a pesticide or device collected. Collect computer-generated records indicating shipments/sales of suspect pesticides or devices. Identify these records in the same manner as the physical or documentary sample itself. A Statement (EPA Form 3540-42; see Exhibit 1-1) signed by the dealer, identifying both the lot sampled, and/or the applicable records should be collected. Have the dealer sign and initial the inspector's copies of the records obtained to prove that he/she provided them on the date of the inspection.

While records collected are not samples, they are identified as "exhibits" to be included and identified in the inspection report and identified with the date of collection and the inspector's initials along with an exhibit number.

Note that distribution and sales records may be in hard copy but also may be in an alternate format. Inspectors should always attempt to obtain hard copy records, if possible, either as copies of individual invoices or as a computer printout of the individual transactions. However, inspectors should be prepared to collect and gather records in other media (electronic records). If distribution/sales records are not available for collection during the on-site inspection, the inspector should request such records by a certain date (i.e., within the next 10 business days).

For inspections conducted using EPA authority, inspectors should obtain records documenting the distribution and sale of each sampled product based on the following protocol:

- When conducting a for-cause inspection or whenever an inspector believes a sample collected is in violation of FIFRA, the inspector should obtain a minimum of fifteen (15) related distribution and sales records for those sampled pesticide products, if available.
- When conducting a neutral scheme/routine inspection and the inspector obtain pesticide product samples but has no reason to suspect that the sample are violative, collect a minimum of five (5) related distribution and sales records per pesticide product sampled, if available.
- Inspectors always have the discretion to collect more than the minimum required distribution and sales records when the inspector believes that, based on his/her

observations during the inspection, gathering the additional evidence would be appropriate.

- Inspectors also have the discretion to request additional records by post-inspection information request or through a follow-up inspection in order to obtain the additional records to adequately document the suspected violative distributions and sales of the sampled product.

INVOICE

The invoice shows the seller's intent to offer the pesticide or device for sale or distribution. It may provide such information as the value of the goods, carrier, and date of shipment. If duplicates or photocopies of the invoice are unavailable, photograph the invoice or copy it by hand on EPA Form 3540-13, Section 1, "Copy of Invoice and Shipping Record" (see Exhibit 1-1). In the absence of an invoice, purchase orders, receiving records, canceled checks and correspondence may be substituted.

BILL OF LADING

The shipper who delivers the goods to the carrier for shipment makes out the bill of lading (BL). It is an order for the carrier to move the goods. When the carrier's agent signs the BL, he or she acknowledges receipt of the shipment. Note that the date the carrier's agent signs the BL is the date of the shipment and this may or may not be the same date that the BL is filled out. The carrier's office in the city of origin of shipment will maintain a copy of the BL. Normally, the following information is found on the BL: (1) name and address of shipper; (2) name and address of consignee; (3) date of shipment; (4) name of carrier; (5) rail car number, if applicable; and (6) a description of the goods. If duplicate copies or photocopies are unavailable, the inspector should obtain a photograph or hand copy the BL information onto EPA Form 3540-13; see Exhibit 1-1.

FREIGHT BILL

This record is completed by the transportation company for the purpose of collecting freight charges. It should include the same information as found on the BL, plus information about the carrier's handling of the shipment and cost involved. Railroads prepare freight bills at their destination offices, where copies can be obtained. Steamship and airline companies usually combine the BL and freight bill into one form. Copies are filed at both the origin and destination offices of these carriers. Truck lines prepare freight bills at the originating office, and both the origin and destination offices should have copies. The pesticide dealer will usually have a freight bill if he/she received the goods directly.

The inspector should obtain a photograph or photocopy of the freight bill or, if necessary, hand copy the freight bill information on to EPA Form 3540-13; see Exhibit 1-1. Enter the type of shipping record in block 23 of the form. Sections 1 and 11 may be executed together on one sheet if necessary. If only one section is used, leave the other section blank and submit the entire page of Form 3540-13.

WAYBILL

A transportation company uses a waybill in its own operations. The waybill accompanies the shipment during transit. Shippers or consignees do not receive copies of waybills but the inspector can obtain them from the carrier, if necessary. Other transportation records are generally more readily available than waybills. Airfreight waybill numbers are designed so that the originating line and point of origin are encoded within the waybill number. Each airline has a numerical code description indicated by the first two digits of the number. The three subsequent letters indicate the point of origin.

For example, waybill number 01LGA designates American Airlines (01) as the carrier and La Guardia Field (LGA) as the point of origin. Most airline offices have a copy of "Official Air Freight Transmittal Manual," which lists all the codes. Photograph or hand copied the waybill into section 11 of EPA Form 3540-13, if duplicate copies or photocopies are unavailable.

MAIL OR PARCEL SERVICE SHIPMENTS

Marketplace samples—Attempt to obtain the original packaging that contains the address sticker. If the original packaging is not available, the inspector should get a signed statement (EPA form 3540-42, see Exhibit 1-1) from an individual with knowledge of the shipment. The statement should contain the facts concerning the shipment.

Induced samples—When the inspector receives an induced sample directly by mail or parcel service, the sample documentation should include the portion of the wrapper showing name and address of the sender, the postmark or postage meter tape or any shipping marks. A copy of the air bill or other shipping record is also to be maintained as part of the sample documentation. Other necessary records include photocopies of the money order or cancelled check, the letter placing the order and the original advertisement.

SHIPMENTS BY NONCOMMERCIAL VEHICLE

When a vehicle operated by the shipper or dealer was used to ship pesticides/devices and no commercial shipping records are available, the inspector should obtain a statement of the facts concerning the shipment. The inspector should use EPA Statement Form 3540-42; see Exhibit 1-1. The statement should cover the facts known to the dealer regarding the actual point of origin, the date of shipment, the ownership and operator of the vehicle, and the invoice from the shipper or the dealers receiving, warehousing and/or inventory records.

STATEMENT

Obtain a Statement (EPA Form 3540-42, see Exhibit 1-1) from persons who have dealt with the pesticides/devices or records sampled and who have relevant and pertinent knowledge. Statements are in writing and signed by the person writing the statement. A statement fulfills the same function as an affidavit, but differs in that it is not under oath. See, Chapter 16, "Inspection Reports and Supporting Documentation," for more information on Statements.

SAMPLE PREPARATION, CUSTODY AND HANDLING

IDENTIFICATION OF SAMPLES AND LABELS

Identify each sample with the inspection sample sequence number (any sample or subsample number), the date (mm/dd/yyyy), inspector's credential number and inspector's initials. Write this information with permanent ink (e.g., permanent marker) on the container so as not to obscure any portion of the label(ing) or package. When more than one unit is collected, identify each unit with a separate sample number. If it is necessary to take subsamples of the main sample, these can be identified as extensions of the main sample number (e.g. 12345-001 or 12345-A). All collateral labeling, including circulars and inner instruction sheets, should be similarly identified. Circulars that have been removed from the sample for identification should be reinserted into the original packages.

Additionally, when identifying larger size unit samples, unless identical bin labels are not available, make a hand-written label for each subsample that provides at least the following information for the safety of those who will handle the sampled product:

(1) brand name of the product;

(2) principal active ingredients and labeled concentrations in percent;

(3) company or name and address as shown on label;

(4) distinguishing marks or code numbers;

(5) "poison" and skull and crossbones stamped in red ink if the product's label was so marked (poison labels must also be affixed to the outside of the sample bag); and

(6) the EPA Registration Number, if present.

The above instructions also apply to all small-sized samples that are wrapped and sealed in such a way as to obscure the product's label. Copies of appropriate bin labels can be taped to each container, if available, in lieu of the above information.

IDENTIFICATION OF DOCUMENTS

RECORDS

Identify all sample records collected, in the inspector's handwriting, by including the inspection sample sequence number, the date and the inspector's initials. This identification should appear as close to the upper right corner as possible. The inspector should also identify each original record in the same manner or on the reverse side of the original document(s). Return the original(s) to the facility at the closing conference after making copies.

ACCOMPANYING LITERATURE, LABELING, PHOTOGRAPHS AND EXHIBITS

Identify this material, in the inspector's handwriting, by including the sample number, date and initials. Do not mark on the face of photographs. All identification marks should be on the border of the photograph. Each photograph should be identified as to which panel of label it represents (i.e., front panel, back panel, left side or right side panel). A photograph showing the entire label and its placement on the container should be submitted. If it is a black and white photo, a notation of the color of the warning statement should be made on the photograph. Document the source of any accompanying labeling or literature collected in the inspection report (or equivalent narrative). When using digital photography the inspector should follow the guidelines in the Digital Image Guidance for EPA Civil Inspections and Investigations.

SAMPLE CUSTODY AND INTEGRITY

Chain of custody begins when the inspector obtains the sample and properly identifies it; this establishes custody of the sample and ensures integrity of the evidence.

Samples are prepared by placing the sample(s) in an inverted clear polyethylene bag (4-mil thickness). It is important that the sample label be readable through the plastic bag. Seal each sample in a separate bag. In addition to ensuring custody, the polyethylene bag provides some degree of containment in case of breakage or leakage.

Evidence bags are also an acceptable means of securing a sample and establishing custody. NOTE: Evidence bags have an identifying area on the bag to be completed by the inspector with a permanent marker and a tear-away strip to be identified and included with the Inspection Report and/or the Inspector's copy of the Receipt for Samples.

THE EPA OFFICIAL SAMPLE SEAL AND POLYBAGGING

All physical samples are sealed officially by placing a completed EPA Official Sample Seal (EPA Form 7500-2, Exhibit 1-1) with the signature of inspector, sample number, date, name and title of inspector printed. There is also space for a regional office location to be noted on the form.

1. Use the sample preparation procedures described above.

2. Invert the polybag (turning inside out) to have the sealed seam inside the polybag.
3. Place the identified sample(s) in the polybag.
4. Twist the top of the polybag and tie a knot in the bag. Note: leave enough room at the top of the bag to fold down over the knot.
5. Fold the top of the polybag down over the knot and re-twist the bag.
6. Apply monofilament, masking or other type tape around the polybag, at the area just below the knot.
7. Complete the EPA Official Sample Seal (EPA Form 7500-2,see Exhibit 1-1) and peel away the backing of the Seal.
8. Apply the Seal around the taped area of the bag by bringing the two ends of the seal together, and then press the seal together until it reaches the bag area.
9. Secure the sample(s) assuring chain-of-custody procedures until the sample(s) are sent or delivered to the laboratory.

If it becomes necessary to break an official seal, remove the seal from the bag and then initial and date the seal. Then mount the broken seal on a piece of paper and include it with the inspection report to provide a continuous history of the sample. Re-seal the sample with a new EPA Official Sample Seal. This should be noted in the Chain-of-Custody Record (EPA Form 3540-41; see Exhibit 1-1).

SAMPLE INTEGRITY AND TRANSFER

The procedures governing sample integrity and sample custody begin from the point of collection and continue through each transfer of the physical sample. Sample integrity refers to steps necessary to ensure that nothing has compromised the chemical or physical integrity of the sample. Sample custody refers to the steps necessary to verify where the sample has been and what has happened to it, documented in a Chain-of-Custody Record (EPA Form 3540-41; see Exhibit 1-1).

Following collection, documentation, and initiation of chain-of-custody, samples must be stored in a secure area prior to transfer to the laboratory. Transfer pesticide product samples to the laboratory, in order of preference, either by: (1) direct personal transfer or (2) common air or ground carrier.

General guidelines:

(a) Samples should be submitted to the laboratory within five days of collection;

(b) Glass containers must never be packaged directly against each other, either within the same plastic bag or within the shipping container;

(c) If necessary, provide refrigeration or freezing during shipment;

(d) The sample label, whether for a prepackaged unit or for sub-sampled material, should always be readable through the plastic bag;

(e) Liquid samples should not be packaged with solids in the same outer shipping container;

(f) A copy of the Investigation Summary Report or equivalent form, if used, should be included with the samples, protected in a protective bag or sleeve;

(g) The laboratory director or designee should be notified by telephone that the samples are being shipped, the mode of transfer and the expected arrival date;

(h) Use packing materials and adsorbent materials to help prevent spills and contamination during shipment; and

(i) Provide the lab with any pertinent information with regard to the sample(s), including information on the solvents(s) that were used to clean the sample container, sampling equipment.

(j) Safety Data Sheet (SDS) for the product should be included in the shipment.

MODE OF TRANSFER

HAND DELIVERY

Hand delivery to the laboratory is the preferred method of sample transfer. Follow all requirements for sample integrity and sample custody, as set forth above. Any authorized individual may transfer official samples to the testing laboratory as long as all such transfers are fully documented with respect to dates and signatures on the Chain-of-Custody Form (EPA Form 3540-41; see Exhibit 1-1).

COMMON CARRIER

If pesticide formulation or related samples cannot be hand-delivered to the laboratory, the services of a commercial shipping or overnight package firm (either surface or air) are preferred. Note that the United States Department of Transportation (DOT) regulates transportation by common carrier, particularly concerning the conveyance of hazardous materials, which includes many pesticides. DOT requires that persons responsible for working with hazardous materials (hazmat) must have hazmat training.

Because DOT regulations are frequently updated, the pesticide inspector is advised to obtain the latest edition of these regulations to ensure full knowledge of pertinent additions and deletions (49 C.F.R. 105 through 199). Many pesticides are listed in the Hazardous Materials Table in 49 C.F.R. 172.101 or are listed according to their hazardous properties as being poisons, oxidizers, corrosives, flammables or pressurized gases.

In most cases, the pesticide label can be used to identify the hazard category, as the EPA Pesticide Registration Division classification system is almost identical to that being used by DOT. The DOT table cites the appropriate labeling, maximum quantity that can be shipped per package and specific regulation requirements and exemptions for packaging. The Hazardous Materials Table also contains an appendix that gives the reportable quantities for certain materials. These are quantities that must be reported on the shipping papers, if appropriate, to meet EPA reportable release requirements.

For quick reference, see the DOT publication, "How to use the HMR."

Two major parcel service companies, United Parcel Service and Federal Express, each have toll free numbers to assist the inspector in the use of their services for transporting hazardous materials.

Federal Express	1-800-463-3339	http://www.fedex.com/us/
United Parcel Service	1-800-322-1333	http://www.ups.com/

Pesticide formulations that do not fall under any of the hazardous categories may be shipped as unrestricted. However, packaging should at least meet the requirements of the DOT ORM-A classification (49 C.F.R. Part 173).

U.S. POSTAL SERVICE

Except in emergencies, the U.S. Postal Service should only be used to transfer small quantities of nonhazardous solid pesticides formulations to the laboratory, such as antimicrobial pesticides of low concentration (below 5%). Specific restrictions exist on the mail-ability of poisons, flammables, oxidizers and corrosives and explanations are provided in the USPS Publication 52 - Hazardous, Restricted and Perishable Mail. Ship all samples by Registered or Certified Mail with a Return Receipt Request in order to maintain proper chain-of-custody.

EXHIBIT 6-1: EXAMPLES OF RECORDS

The following are examples of records that an inspector may obtain during an inspection:

- **Market Place Inspection and Sampling**
  - Invoices
  - Shipping records
  - Bills of lading
  - Freight bills
  - Waybills–if imported by or exported by air
  - U.S. Mail or commercial carrier shipping records
- **Producer Establishment/Dealer/RUP Dealer Inspection and Sampling**
  - Invoices
  - Shipping records (of received manufacturing use or technical products)
  - Bills of lading
  - Freight bills
  - Waybills – as above
  - U.S. Mail or commercial carrier shipping records
  - Export records
  - Foreign Purchaser Acknowledgement Statement
  - Child resistant packaging records
  - Certification statement
  - Test verification
  - Packaging /Re-packaging agreement(s) or contracts
  - List of acceptable containers
  - Supplemental registration agreements and re-packaging agreements
  - Sources of all technical (manufacturing use) pesticide products or chemicals (copies of all documentation of the purchase of these materials (invoices, shipping records, bills of lading, etc.)
  - Guarantees offered for each product (copies)
  - Records of disposal of residues, old chemicals, etc.

- Records of sale of RUP products to certified applicators
- Inspection and maintenance records for refillable containers

CHAPTER SEVEN
RESIDUE AND ENVIRONMENTAL SAMPLING

CONTENTS

Introduction 3
General Sampling Guidelines 3
Sampling Plan 4
Technical Data 4
Weather Data 5
Sample Selection 5
Sampling Equipment 6
Incident Site 7
Sample Containers 8
Receipt for Samples 8
Sample Collection and Preservation 9
Grid Sampling 9
Foliage Sampling 9
Discrete Foliage Sampling 10
Composite Foliage Sampling 11
Grid Pattern Foliage Sampling 11
Crop Damage Residue Incidents 12
Human Exposure Incidents 13
Property Loss Incidents 14
Agricultural Pesticide Misuse 15
Structural Pesticide Misuse 16
Soil Sampling 16
Discrete Soil Sampling (Known Depth) 16
Grid Pattern For Soil Sampling 18
Composite Soil Sampling 19

Discrete Sediment Sampling 19
Water 20
Discrete Surface Water Sampling 20
Air 20
Air Sampling Indoors 21
Air Sampling Outdoors 21
Animal, Birds, Fish and Bee Sampling 21
Surface Wipe Sampling 22
Discrete Surface Sampling 22
Grid Pattern For Surface Sampling 23
Clothing 23
Sampling in Support of Residue and Environmental Sampling 23
Pesticide Formulations (Technical Grade) 24
Tank Mix 24
Sample Storage, Preservation and Shipping 25
Storage and Preservation 25
Shipping Procedures 26

RESIDUE AND ENVIRONMENTAL SAMPLING

INTRODUCTION

Residue and environmental sampling may be necessary when there has been a spill or when there is suspected pesticide misuse. Suspected human, animal, crop, or environmental contamination can require quick action to determine exposure or to prevent contaminated commodities from entering the food chain. Pesticides that degrade quickly will require sampling soon after their application to detect their presence.

A sample should support an allegation that a violation has occurred. Therefore, the sample must conform to the rules regarding admissibility of evidence; specifically, the inspector must document how the sample was obtained and then establish the chain of custody by proving where the sample has been and how it was treated since it was collected.

GENERAL SAMPLING GUIDELINES

The following general guidelines apply:

- Make a sampling plan and be prepared to adapt it to the requirements of the individual investigation.
- Have and use the necessary sampling tools, containers and personal protective equipment appropriate for the particular inspection.
- Do not contaminate yourself or cross-contaminate the samples. Always wear clean disposable gloves, protective clothing and safety equipment as required by the pesticide label, regulations and policy when entering fields/areas or handling samples. Change gloves between each sample collected. Change protective clothing as needed. See Chapter 2, “Health and Safety.”

Composite sample - A combination of two or more sub-samples to produce a homogeneous sample. Composite samples are used to identify suspected chemicals when the area, crop or material is suspected to be uniformly contaminated.

Duplicate samples - Two or more samples collected from the same area having comparable conditions.

Split sample - The division of a sample into two equal and identical portions. This is usually done at the laboratory.

Use dilution sample - A use dilution is a formulated pesticide that has been blended with a carrier such as water, and is ready to be applied by an end user. If the use dilution is made with a concentrate, a sample of the concentrate should also be obtained for analysis. Additionally, a photograph of label(ing) and container of the concentrate should be obtained.

Residue sample - A residue sample is usually collected from the natural environment (soil, water, vegetation, bees, hives, fish, animals), but may be from non-environmental sources. A residue sample is collected for a variety of reasons, but usually to determine if pesticide residues are present in the media sampled. Swab samples may also be taken to detect residue on an object. Collect residue samples in accordance with federal sampling procedures. Sample containers must be identified with the sample number, the date and the inspector's initials. Take photographs and draw a diagram of the area so that they will be accurate depictions of what the inspector did and/or observed in the sampling area. Photographs should be identified in the same manner as the sampling container.

Control Sample - Prior to sampling, take a control sample when investigating an incident site. Take the control sample from an area outside of the incident site. This will help establish the boundaries of the incident.

SAMPLING PLAN

A sampling plan is necessary as a framework for the inspection. It enables the inspector to gather all relevant information needed before, during and after the inspection. At times there may be information that can be gathered prior to sampling. However, often there will be time constraints that reduce the ability to collect certain data prior to sampling. To develop a sampling plan, review any available notes, statements, permits, use reports and technical data on the alleged pesticides involved.

TECHNICAL DATA

Technical data will assist in determining sample types, methods and location, a time frame in which to collect samples and whether there should be any special handling or sample preparation procedures. The inspector may benefit from referring to the *Farm Chemicals Handbook, Crop Protection Chemicals Reference, Pesticide Product Description,* which contains information on toxicology and is commercially available. The following represents technical data that may be useful to the inspector:

- Chemical properties
    - Formulation
    - Half-life

  - Metabolites
  - Physiological and biochemical behavior
  - Foliar absorption characteristics
  - Translocation action
  - Behavior in or on soils
  - Absorption and leaching characteristics
  - Microbial breakdown
  - Loss from photodecomposition and volatilization
  - Hydrolysis
- Toxicological properties
  - Toxicity to humans/wildlife/fish
  - Acute/chronic toxicity
  - Poisoning symptoms
- Laboratory qualifications
  - Method of analysis
  - Analytical sensitivity
  - Availability of method and/or reference standard(s)

WEATHER DATA

Weather data, at the time and place of incident occurrence, if available, will help in determining drift patterns, volatilization rates, off-target movement of pesticides, etc. This information can be obtained from the National Weather Service, local agencies and airports:

- Wind speed and direction
- Rainfall
- Temperature
- Inversion
- Humidity

SAMPLE SELECTION

Selecting the sample type(s) will depend on the type of incident that allegedly occurred. For example, if the incident involved:

- Drift of a pesticide on people—the sample type could include total foliage (i.e., total residue on foliage) in a gradient pattern and clothing of the contacted person(s).
- Drift of pesticide on people harvesting a commodity—the sample types may include total foliage in gradient pattern, total commodity, dislodgeable foliage and clothing.
- Misuse of a pesticide resulting in animal, fish or bee kills – the sample types may include dead animals, fish, bees, honey and pollen as well as foliage samples or swab samples.
- Misuse of a pesticide in a confined space —the sample types may include various soil samples and surface wipe samples.
- Crop damages from run-off containing a pesticide—the sample types may include total soil or total foliage in a gradient pattern, total commodity and total plant.
- Fumigation of places like railcars, ships, containers, grain silos, or bins, homes or structures —the sample types may include a sample of the commodity and a photograph of any placard that provided notice of the fumigation.

Note that when sampling in confined spaces, such as crawlspaces, railcars, ships and containers, additional safety precautions should be followed. See Chapter 2, "Health and Safety."

The purpose of sampling is to collect evidence to determine if a violation occurred. An investigator will have to use his/her best judgment in selecting the appropriate sample types based on the information gathered. For drift incidents, the inspector will need to determine when the pesticide in question was applied, so as to decide whether to sample vegetation or soil. If the available plants have a heavy canopy, thus allowing limited soil exposure to direct spray, vegetation should be chosen as the sample of choice. If vegetation at the incident site is limited, excessive time has passed since the application, there is new plant growth or heavy rains could have reduced the concentration, soil should be the sample of choice.

Whatever sample type is used, a sample must be representative of the media being sampled if it is to provide the basis on which to determine that a violation exists. This requires the selection of sampling points that will be representative. In addition, keep in mind the statistical considerations that affect representative sampling, such as variability in sample collection methods; frequency of samples taken over a period of time; and number of samples collected.

SAMPLING EQUIPMENT

Use clean sampling containers. Sampling containers may include bottles, metal cans, triers and aluminum foil. Sampling containers should be new or have been properly cleaned. Prior to use, containers should be washed and rinsed with hexane or isopropyl alcohol, and permitted to air dry. **(NOTE: Decontaminate containers used to sample sulfonyl urea pesticide products in a 5% solution of chlorine for 1 minute of contact time.)** Note what solvent was used to clean and decontaminate all sampling equipment and sampling containers on the Receipt for Samples.

All sampling equipment must be stored in the office or locked vehicle in an uncontaminated designated location. For smaller equipment, an enclosed, airtight container is recommended. Larger equipment can be wrapped in an uncontaminated cloth or stored in a polyethylene bag but will need to be cleaned and decontaminated again prior to use.

Equipment, gear and items that may be useful for taking samples include:

- Notebook, notepaper, computer or other electronic device used to record information, camera.
- Clear plastic bags (4 mil thickness), jars and/or cans with lids (various sizes) and aluminum foil.
- Commercially available evidence bags that are pre-printed with chain-of-custody and evidence fields to be filled in by the inspector.
- Personal safety equipment and clothing, such as coveralls, respirator, goggles, hardhat, powder free disposable and rubber gloves, boots, rain suit, waders.
- Labels, tape, stapler, evidence tags, official sample seals or evidence tape, masking tape.
- Shovel, hand spade, knife, pruning shears, trowel, spatula or leaf punch.
- Hexane, isopropyl alcohol, distilled water and paper towels.
- Sterile wipes and precut templates of a size equal to 4”x4” opening in the center.
- Measuring tapes, stakes, camera, film, extra batteries, extra SD Card and accessories.
- Ice chests (coolers, styrofoam), re-useable freezer packs, wet ice or dry ice (caution: do not handle dry ice with bare hands or allow samples to directly contact the dry ice).
- Permanent markers, pencil, pen, note pad and record book.
- County or city map, aerial maps and topographical maps, global positioning system (GPS) device.
- Disposable core tubes and siphon tubes.

INCIDENT SITE

Survey the incident site and create a site diagram depicting the following:

- Structures.
- Crop type, maturity, acreage.
- Physical surroundings as landmarks:
    - Telephone poles (note the ID number on the pole) adjacent to crops.
    - Roads, streets, buildings and other important identifying factors.
    - Sampling medium (foliage, surface areas, etc.)
    - Trees.

- Waterways.

- Location of workers.
- Crop/plant damage.
- Spotting on leaves, walls, floors, vehicles.
- Pesticide containers in storage.
- Location of odor complaint, if applicable.

Draw the diagram of the incident site as near to scale as possible with north at the top. As samples are collected, identify their location(s) and distances on the diagram. The diagram must be large enough to include all of the details and be legible.

SAMPLE CONTAINERS

Identify all samples collected with the sample number (and sub-sample number, if applicable), date and inspector's initials and place them in a large 18"x 30", inverted, heavy polyethylene bag or evidence bag. Seal the polyethylene bag as follows:

- Twist the top of the bag and tie a knot in the inverted bag.
- Fold the top of the bag down over the knot and twist the bag around the knot.
- Apply several wraps of masking, duct or monofilament tape below the knot.
- Apply the EPA Official Sample Seal (EPA Form 7500-2, see Exhibit 1-1)(or if a state/tribal inspection, the equivalent state/tribal sample seal) around the tape. Identify the official sample seal with the sample number, date, city and state of collection and the inspector's name and signature.

For one-liter amber containers:

- Tape individual containers around the cap and deep into the neck with masking, monofilament or duct tape.
- Place the inspector's initials across the tape.
- Follow all other procedures for identifying, logging and sealing the sample.

RECEIPT FOR SAMPLES

Fill out a Receipt for Samples in ink and include a copy with the samples sent to the laboratory. Place the Receipt for Samples in a separate sealed plastic bag to prevent moisture absorption. Note that this is in addition to the Receipt for Samples given to the owner or operator of the

property where the sample collection is being conducted. On the Receipt for Samples being sent to the laboratory:

- Identify the sample material as accurately as possible.
- If possible, identify specific pesticides or classes (e.g., organophosphates, phenoxys) suspected to have caused the problem. Also include the phrase "WARNING PESTICIDES" on the Receipt for Samples to warn laboratory personnel.
- Copy identifying numbers on the sample container exactly on the Receipt for Samples to identify the sample for the laboratory.
- Identify the solvent (if any) used to clean sampling equipment.

SAMPLE COLLECTION AND PRESERVATION

Physical pesticide sampling may include concentrated pesticide formulations, diluted pesticide solutions, and any substance or material suspected to be contaminated (environmental residue samples).

GRID SAMPLING

Grid pattern sampling is recommended for incident sites because it represents a logical, systematic approach to collecting samples. The particular grid pattern is created once the inspector arrives at the incident site. The grid is intended to measure the extent of contamination at the whole site. Each point on the grid represents a location where a sample is taken. Grids should be constructed to begin sampling at the point of least suspected contamination and working towards the point of greatest suspected areas of contamination. The number of points on the grid, as well as the distance between each point, will be at the inspector's discretion. Note the grid location for each sample taken. When grid sampling is completed, the inspector should create a diagram of the grid and include it with the inspection report. Grid sampling will be discussed with more specificity in the sections below on the Types of Residue and Environmental Samples.

FOLIAGE SAMPLING

Pesticide drift or other misapplications of pesticides are often documented by sampling and analyzing foliage or whole plants for residues. The sampling techniques described below are applicable for most agricultural crops as well as nonagricultural vegetation.

DISCRETE FOLIAGE SAMPLING

Collect foliage from specific areas in the field. The purpose of collecting the sample from specific areas is to identify residue delineation between the sample areas and to maintain sampling uniformity. It is important to identify the location of the sample site within the field because the sample and incident site diagram may be used as evidence in an administrative or judicial action. The size of the sample area will vary with the type of location.

At all sites, collect a control sample from an area with vegetation similar to that within the affected areas. It is absolutely critical that the control sample be taken from an area known to be free of any contamination from the pesticides in question. A contaminated control sample will destroy the usefulness of other samples as evidence.

Collect samples in a sequential order from the least anticipated residue concentration to the greatest anticipated concentration (i.e., control, suspected drift area, then target area). This will help reduce the potential for cross-contamination of samples. Take enough samples to establish boundaries of contamination. (The lab can always discard unnecessary samples later. It is rarely possible to collect additional samples afterward.)

For field crops and non-crop areas (weeds, fallow fields, etc.), the size of the sample site should be approximately a 25-foot square (or 625 square feet).

For orchards and ornamentals, collect samples from approximately four mature trees/vines (rectangle or square area). The area will vary depending on the size of the incident site, the size of the plants and foliage within the site and the number of samples intended to be collected.

Remember, measure the sample area and record it in the investigative notes.

Try to collect foliage of similar type (e.g., grasses or broadleaves only), if possible. It will make it easier to extrapolate the data. If similar type foliage is not available throughout the sampling area, collect different types of foliage. Place each type of foliage in different containers.

Select foliage from all sides of the plant or tree unless drift is suspected. In this case, collect the foliage from the side of the plants allegedly exposed to the drift. For most situations, collect the foliage from the outer leaves of the plant or tree. It may be necessary to uproot the whole plant if systemic pesticide absorption is suspected. Do not select foliage that is in contact with soil. Only collect leaves; do not include twigs or branches. Remember, new growth which was not subject to chemical application may affect the results of an analysis.

Collect enough foliage from the specific sample area to permit proper analysis or screening. If composite, duplicate or split samples are requested, increase the sample size accordingly. Contact the laboratory if in doubt regarding sample size.

Vegetation samples must be wrapped in aluminum foil (pre-rinsed with hexane or isopropyl alcohol and air dried) and placed in large 18” x 30”, inverted, heavy polyethylene bags or evidence bags; alternately, vegetation samples can be collected in glass containers.

Chill, refrigerate, or freeze samples as soon as possible. An ice chest, containing bagged ice or re-useable freezer packs, can be carried into the field for this purpose. If samples are frozen after collection, they must remain frozen. See section on Sample Storage, Preservation and Shipping.

Ship samples to the laboratory as soon as possible after they are collected, following proper chain-of-custody procedures.

COMPOSITE FOLIAGE SAMPLING

Composite samples are taken to determine whether an area is contaminated and to determine whether more thorough, discrete sampling is warranted. After taking a control sample, a composite sample is made up of several sub-samples that are of equal volume or weight and are combined to represent a field or site.

GRID PATTERN FOLIAGE SAMPLING

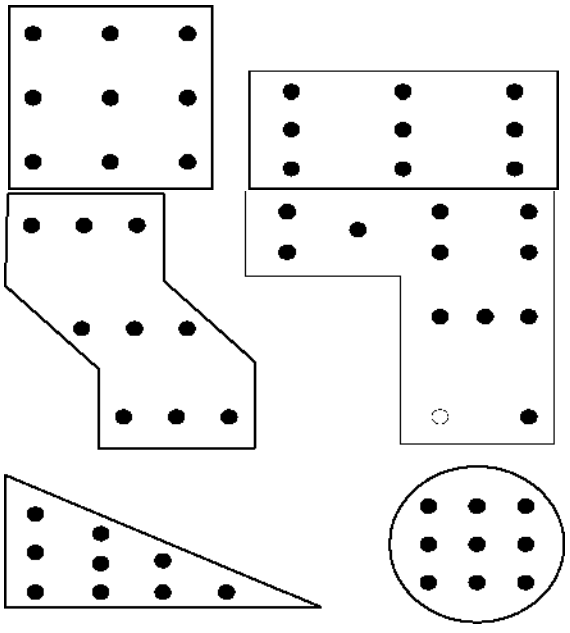


FIGURE 7-1: GRID PATTERN EXAMPLES FOR FOLIAGE

If misapplication to part of a field is suspected, but the treated area is unknown, this type of sampling pattern should be used to help identify the treated area.

Collect samples in a grid pattern following the procedures indicated for a discrete foliage sample. Each sample represents one point on the grid for that field or site, therefore, do not composite them.

After a control sample is taken, the sampling grid pattern in the incident site should start from the edge of the field, depending on the field size. As a rule of thumb, the distance from the edges should represent approximately 10 percent of the width and length of the field or site. For example, a site 1,000 feet wide and 2,000 feet long (approximately 46 acres) has a starting point 100 feet in from the width and 200 feet in from the length. Samples should be in line with, and at an equal distance apart from, one another in the grid pattern. Record the sample locations in the investigative notes and diagram(s).

If using the grid pattern to establish drift, collect at least one additional sample from each of the adjacent fields that are suspected of being the source of contamination.

Each foliage sample from a site should be of similar type and taken from the same location on the plant/tree. Identify the location and area from which each sample was taken on the diagram with distances from landmarks, from field borders and between samples clearly indicated.

CROP DAMAGE RESIDUE INCIDENTS

After taking a control sample, take samples in a line, at approximately equal intervals, from a non-suspected area to the target treated area.

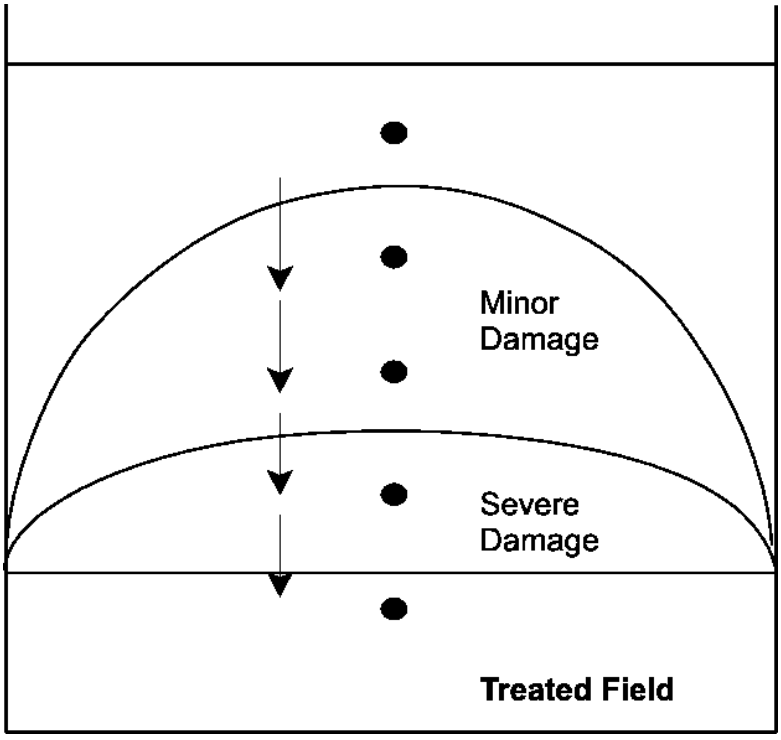


FIGURE 7-2: GRID SAMPLING DIAGRAM - CROP DAMAGE RESIDUE INCIDENT

HUMAN EXPOSURE INCIDENTS

After taking a control sample, take samples in a line, at approximately equal intervals, starting from where there is suspected human exposure and moving outward toward the treated area. These samples will be in addition to wipe samples from vehicles, vegetation/soil samples in grid pattern and clothing samples, if appropriate.

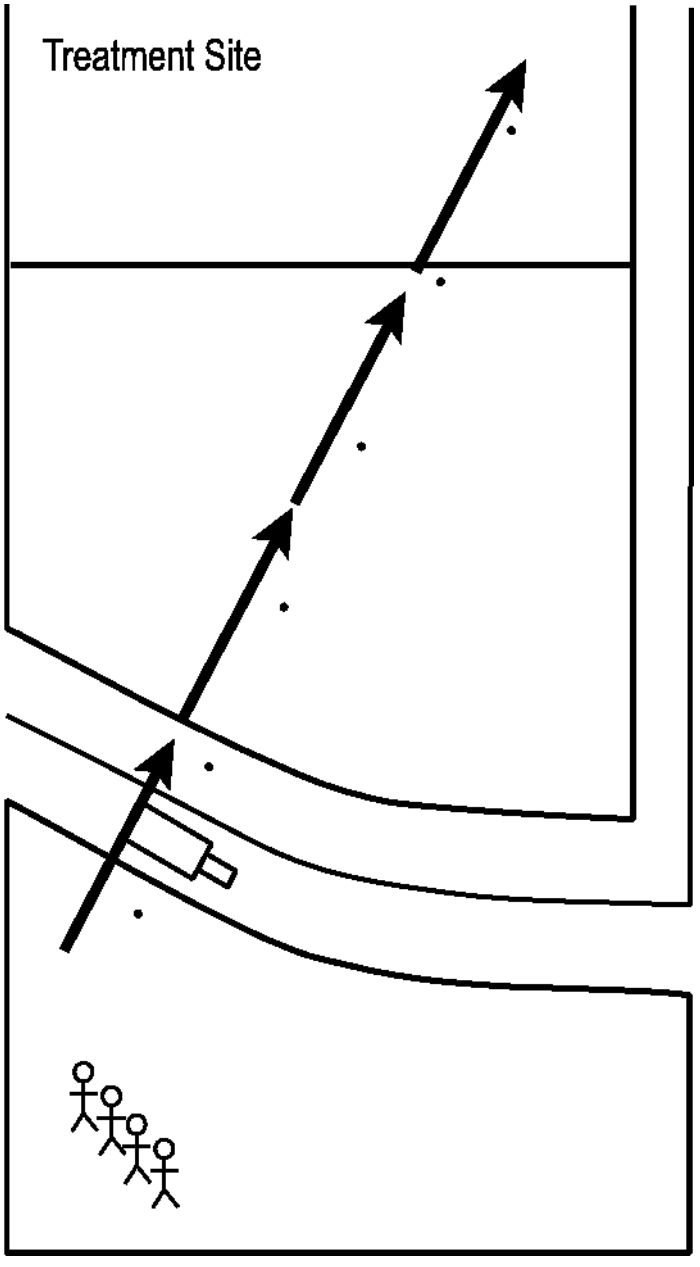


FIGURE 7-3: GRID SAMPLING DIAGRAM - HUMAN EXPOSURE INCIDENT

PROPERTY LOSS INCIDENTS

Where there is suspected property loss or damage that does not involve crop damage or foliage, take samples of the suspected damaged property, as well as vegetation/soil samples in a grid pattern, wipe samples from vehicles and clothing samples, if necessary.

When taking vegetation/soil samples in a grid pattern, take a control sample from outside the treatment site, and then collect samples in a line, at approximately equal intervals, starting from an area of suspected property damage and moving toward the treated area.

When there are multiple areas where pesticide(s) have been applied, the same grid pattern is used as previously described, but samples are obtained in two directions toward the treated areas.

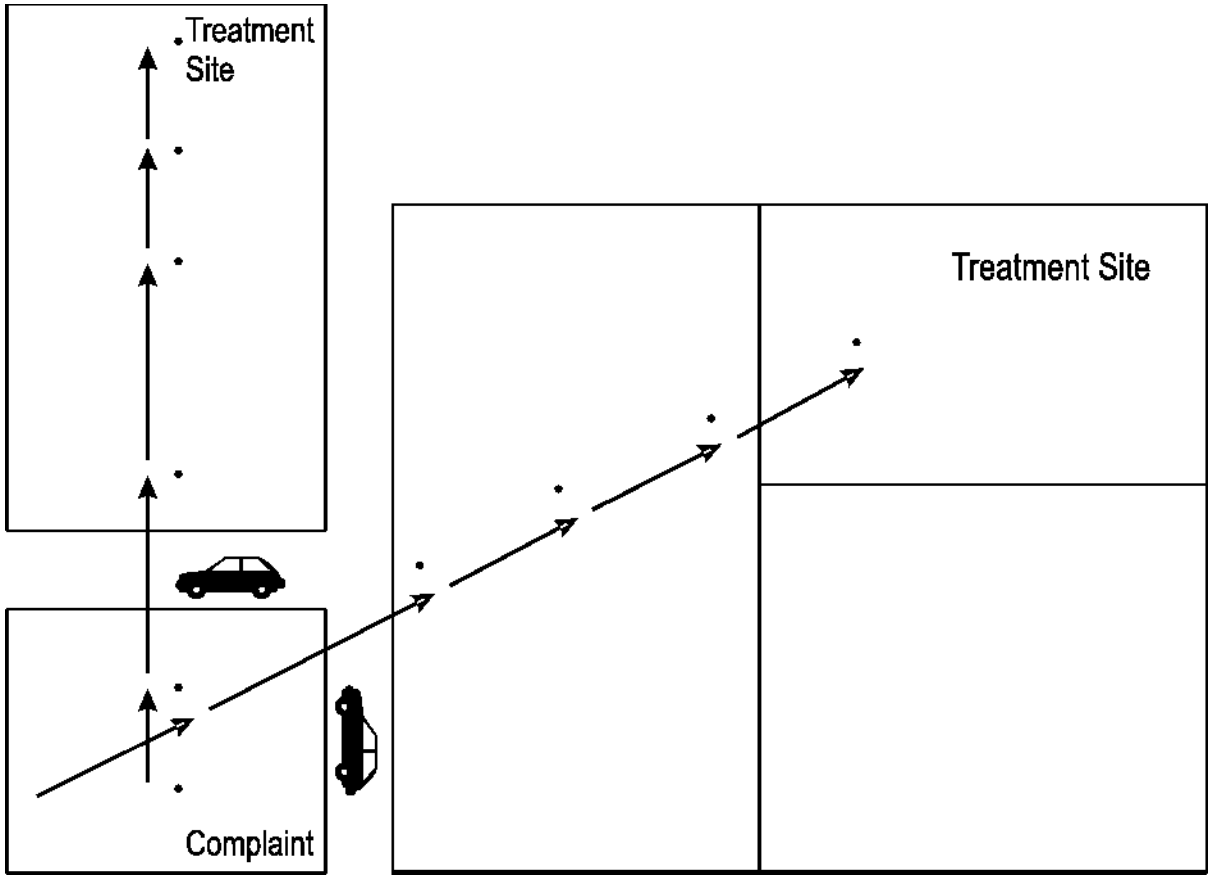


FIGURE 7-4: GRID SAMPLING DIAGRAM -PROPERTY LOSS INCIDENT

AGRICULTURAL PESTICIDE MISUSE

After taking a control sample, take samples in a line, at approximately equal intervals, starting from an area outside the treatment site, ideally where there is suspected exposure, and move toward the treated area. Take vegetation/soil samples in a grid pattern, samples of commodities, wipe samples from vehicles and clothing samples, if necessary.

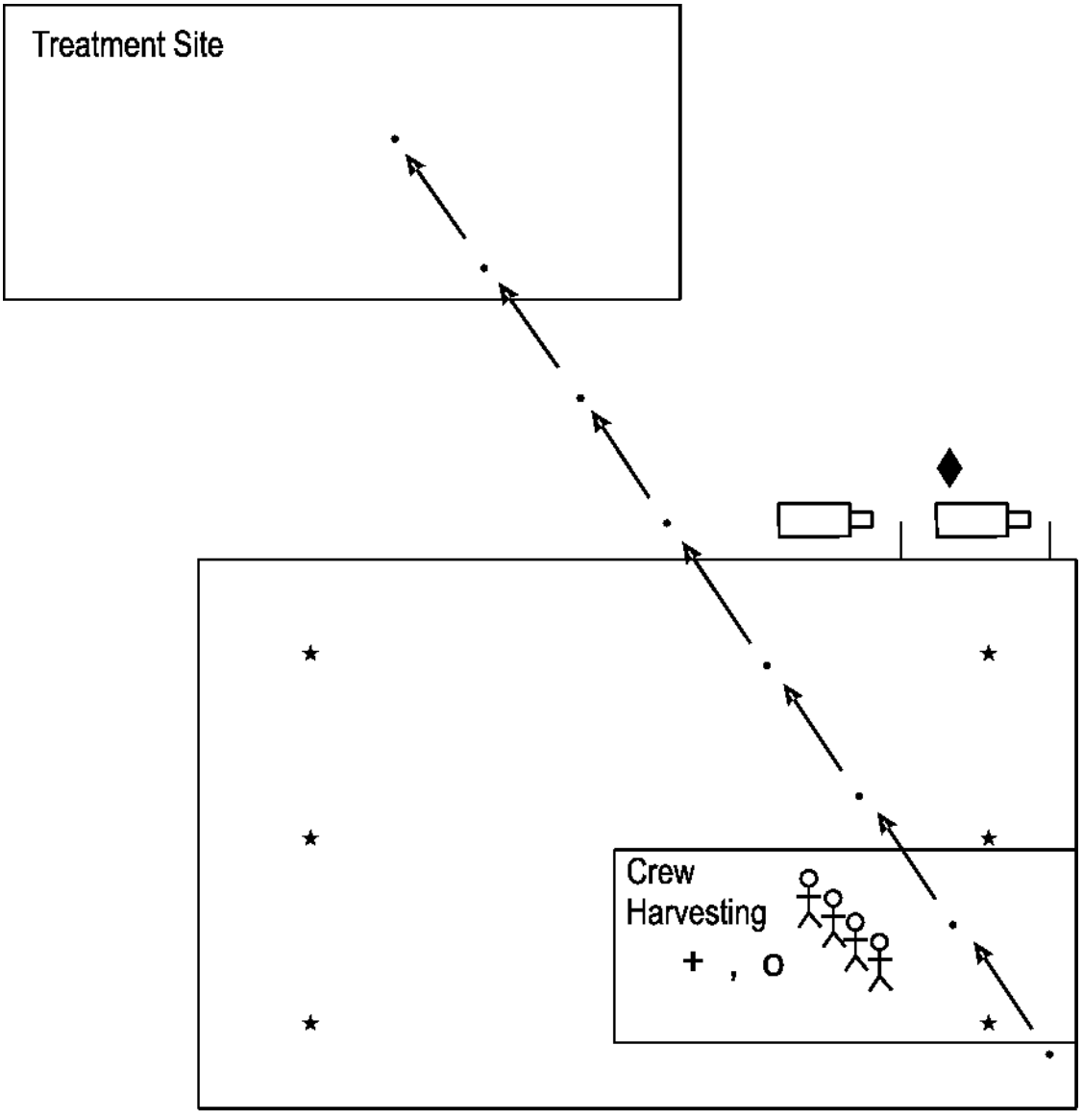


FIGURE 7-5 - GRID SAMPLING DIAGRAM - AGRICULTURAL PESTICIDE MISUSE

STRUCTURAL PESTICIDE MISUSE

Where there is suspected structural pesticide misuse, take a control sample from outside the treatment area. Begin grid sampling outside the treated area and move inward toward the treated area.

Take samples of the suspected damaged property, as well as vegetation/soil samples in a grid pattern, wipe samples from vehicles and clothing samples, if necessary.

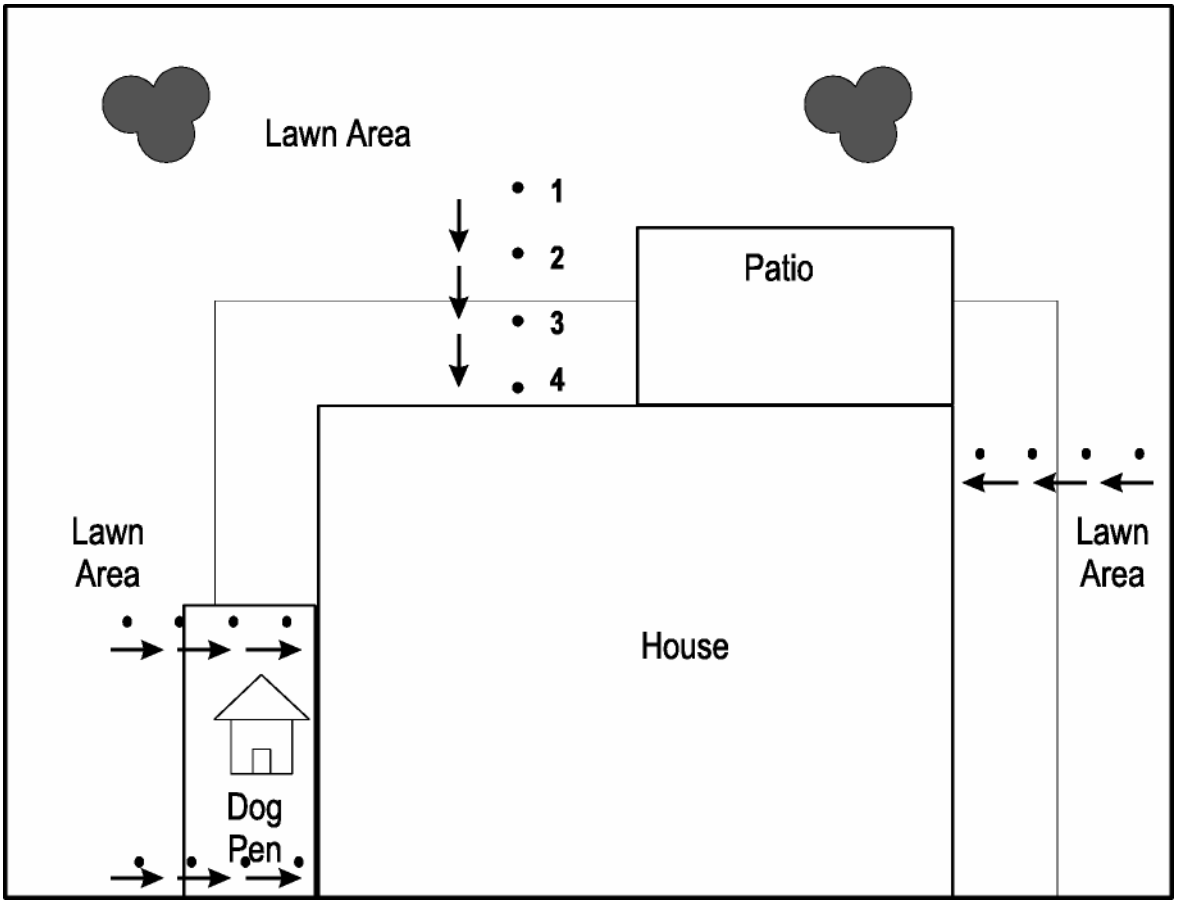


FIGURE 7-6: GRID SAMPLING DIAGRAM - STRUCTURAL PESTICIDE MISUSE

SOIL SAMPLING

DISCRETE SOIL SAMPLING (KNOWN DEPTH)

Collect soil samples at a known depth when the pesticide is suspected of being incorporated, band treated, shanked or moved below the soil surface through leaching. If the samples are not collected at the proper depth, the sample results will be misleading. This type of sampling may be collected in a grid pattern within a field or site.

After taking a control sample, select a specific sample location and measure an area of approximately one square foot. Record the measured sample area in the investigative notes.

If it is suspected that chemical leaching has occurred at the sample site, dig a sampling hole and collect soil from various depths (e.g., 3-6 inches, 6-9 inches). After digging the hole, decontaminate the sampling instrument and clear away the soil at the depth desired to obtain the sample. Decontaminate the sampling instrument and use a clean container to collect the sample.

If a soil probe is available, remove the soil to the beginning depth to sample. Take several core samples to the desired depth using the probe. NOTE: It is not recommended to use the probe when a band or side-dress treatment was used. Since it is difficult to determine where the band treatment is located, the probe technique could miss the pesticide and give misleading results.

SOIL SAMPLING IN FURROWED FIELDS

Chemicals may have been applied in bands or side-dressed in furrowed fields. In order to sample from the appropriate area, a shovel is needed to cut across sections perpendicular to the direction of the furrow at each sample site.

SINGLE ROW

After taking a control sample, start at the center of the furrow and sample across the bed to the center of the opposite furrow. Collect soil from an area 3–6 inches wide and 12-14 inches deep as measured from the top of the bed.

DOUBLE ROWS

If the field is laid out in double row beds, sample from center of furrow to center of bed at 3–6 inches width and 12-14 inches depth.

Mark the location of the sample area on the diagram indicating distances from each sample, depth and width of sample, landmarks and field borders.

Single row beds: combine soil from the area outlined in the figure below and place in a 1 quart container.

Double row beds: Center furrow to center bed.

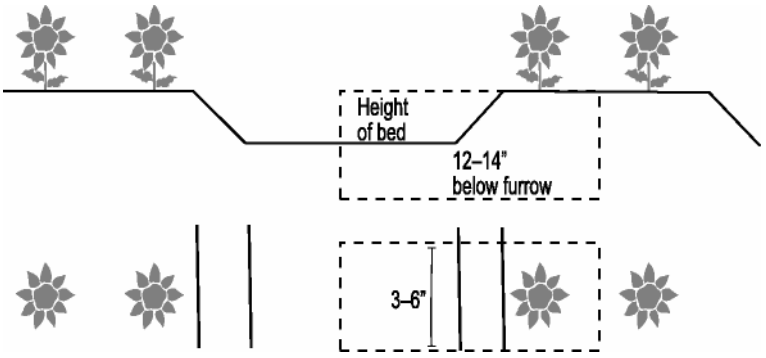


FIGURE 7-7: SOIL SAMPLING IN FURROWED FIELDS

GRID PATTERN FOR SOIL SAMPLING

There are several pesticides (e.g. DCPA and chlorothalonil) that are long-lasting in the environment and adhere to soil particles. Cultivating practices (i.e., disking) and wind can move these particles from adjacent fields to a crop, creating a potential residue problem. Therefore, grid pattern sampling results can be used to document the transport of the soil particles. Grid soil sampling is usually conducted to prove drift from a treated area. If drift is suspected to have occurred to a field and the pesticide can be detected in soil, then grid sampling may be of use.

Collect soil samples at the appropriate depth in a grid pattern following the procedures indicated for a discrete soil sample. Each sample will represent one point on the grid for that field or site. Do not composite these samples.

After taking the control sample, start the sampling grid pattern from the edge of the field, depending on the field size. As a rule of thumb, the closest sample distance from the edges should represent 10 percent of the width and length of the field or site. Each sample should be in line with, and at an equal distance apart from, the other samples in the grid pattern. Record the sample locations in the investigative notes.

Always take samples from an area of suspected lowest concentration and move in a direction towards the area of highest concentration, most likely the treatment site.

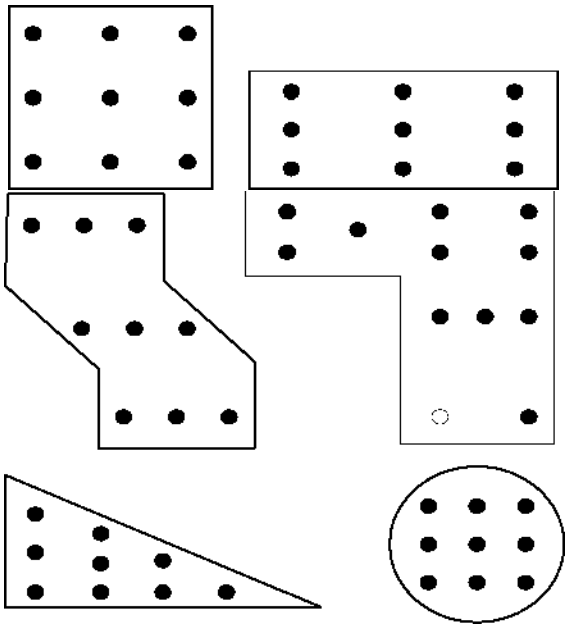


FIGURE 7-8: GRID PATTERN EXAMPLES FOR SOIL

COMPOSITE SOIL SAMPLING

The composite sample is made up of several sub-samples that are combined to represent a field or site. For example, in Figure 7-8, all the grid point samples taken from one area would be combined to make one composite sample. Composite sampling is appropriate in certain specific instances. Where there is a need to merely establish that a pesticide was applied, composite sampling may be used.

DISCRETE SEDIMENT SAMPLING

Pesticide residues can accumulate in the bottom sediment of lakes and streams. It may be necessary to conduct sediment sampling to determine the pesticide source.

There are commercially available devices for sediment sampling, but these devices often require extensive cleaning between sampling to prevent cross-contamination. Directly scooping sediment into a glass container is recommended for shallow sampling situations. Alternatively, a disposable core tube can be used to collect sediment.

To collect the sample, carefully lower the disposable core tube, the container or other sampling device through the water into the sediment. Minimize disturbing the sediment. Retrieve approximately one quart of sediment. Transfer sediment directly into a clean container. Seal with a Teflon or foil-lined lid.

Mark the location of the sample area on the diagram indicating distances from each sample, landmarks and field borders.

Dispose of or clean sampling tools. Rinse the collection container, if used, with hexane or isopropyl alcohol and allow to air dry prior collecting additional sediment samples.

WATER

Pesticide residues may be found in surface water such as lakes, streams or ponds resulting from some type of misuse (i.e., off-site drift, overspray). If pesticide contamination of groundwater is suspected, contact the supervisor to determine the appropriate federal, state or local agency for follow-up.

DISCRETE SURFACE WATER SAMPLING

When sampling surface water, sample as close as possible to the apparent source of contamination. If the suspected pesticide is water soluble, the sample must be drawn from a lower depth. If the pesticide is oil-based, or oil is a part of the tank mix and the alleged misapplication was made across the water surface, then the sample can be drawn from the surface layer.

Use two clean one-liter amber glass containers with an aluminum foil or Teflon seal under a screw cap. If amber glass containers are not available, use two one-quart large mouth containers and wrap each container with aluminum foil to exclude light.

Lower the glass container to the desired depth with the cap on. Remove the cap under water and allow the container to fill. Replace the cap and lift the container out of the water. For samples taken from the surface, dip the container into the water surface and allow it to fill. Containers must be filled completely to the rim, with no air space between lid and the container contents so pesticides cannot volatilize.

It is preferable to take several samples from different locations. Alternatively, a composite sample may be taken by combining sub-samples from different locations around the body of water and combining in two clean one-liter/quart containers.

Mark the location of the sample area on the diagram indicating distances from each sample, landmarks and field borders.

Samples must be chilled or refrigerated and shipped as soon as possible, following proper chain-of-custody procedures. DO NOT ALLOW SAMPLES TO FREEZE. An ice chest can be carried into the field for this purpose.

AIR

Generally, EPA laboratory staff conducts volume air sampling in concert with the inspector. Since they have the unique equipment, chemicals, knowledge and experience needed to operate air sampling equipment, it is recommended that they be contacted if volume air

sampling is needed. The inspector will retain the lead for the investigation and other personnel will assist.

There are two types of air samplers used. High volume samplers are used to measure low concentrations of pesticides over long periods of time and low volume samplers are used to measure high concentrations of pesticides over shorter periods of time. EPA laboratory staff or ESD will make the decision as to which air sampler will be used. Both high volume and low volume sampling equipment draws air through glass cylinders containing a medium designed to capture the pesticides of interest for analysis by the laboratory.

AIR SAMPLING INDOORS

Either high-volume or low-volume sampling equipment can be used depending on expected concentrations. Air sampling equipment produces a moderate noise. It should be positioned where it will not unnecessarily disturb other persons in the structure, if possible.

High-volume sampling equipment must be vented out of the dwelling to ensure that air will not be recycled through the machine.

Rooms with cigarette smoke or gas appliances must be avoided; any gases or suspended smoke particles in the area will contaminate the sample.

AIR SAMPLING OUTDOORS

Sampling equipment must be positioned to avoid exposure to engine exhausts, running motors, cigarette smoke or any other non-target air contaminants.

Sampling equipment must also be protected from rain and direct sprays from application machinery. Shelter hoods are used to protect the equipment in such situations.

Air samples must be sealed and delivered directly to the lab, following proper chain-of-custody procedures.

ANIMAL, BIRDS, FISH AND BEE SAMPLING

Where there has been an animal, bird, fish or bee kill, samples must be taken to substantiate the cause. If possible, sample dead animals, birds, fish and bees before they decompose.

Using disposable gloves, place the small animals, birds and fish in a heavy, inverted polyethylene bag and chill, as soon as possible. At least 500 grams (approximately 1 pound) is needed per sample.

Collect a minimum of four ounces (approximately 1 cup) of dead bees or honey and a minimum of one ounce of pollen from the affected honey bee colonies. It may also be desirable to collect foliage samples or swab samples from around the hive. Since bees can forage several miles

from the colony, samples can be collected of various blooming plants in the foraging area if it can be determined. Remember to collect enough for each analysis. Place each sample in a clean, unused container. See "Guidance for the Inspection of Alleged Cases of Pesticide-Related Bee Kill Incidents" Also, the following website has more information: https://catalog.extension.oregonstate.edu/pnw591.

Chill all animal, fish, birds and bee samples upon collection to prevent further degradation. If decomposition is evident, note on the Receipt for Samples and the Inspection Report.

SURFACE WIPE SAMPLING

Surface wipe sampling is conducted to establish the presence of a pesticide on a surface.

DISCRETE SURFACE SAMPLING

When possible, select a site showing visible residue. Try to avoid areas known to contain waxes because they may interfere with the analysis. Smooth "inert" surfaces are the preferred area to collect the sample (i.e., windshield). Sampling uneven surfaces (such as rugs, furniture, walls, walkways, counters), however, is also possible. Before entering the area to be sampled, take a control sample.

While wearing disposable latex gloves, tape a template to the sample surface. A template can be a piece of cardboard with a four inch square opening. The purpose of the template will be to delineate the sample area at the target site. A new template and gloves must be used for each sample location so prepare as many templates as necessary ahead of time. If a template cannot be placed on target site, delineate the sample area using masking tape laid out to create a four inch sampling square. Photograph the area and templates.

Surface areas are sampled using sterile cotton pads (2" x 3") or filter paper discs moistened with solvent. While wearing disposable latex gloves, pour isopropyl alcohol or hexane over the cotton pad and moisten it completely. Shake off excess solvent. Do not contaminate the solvent by placing the cotton pad over the mouth of the solvent bottle. The target area of the template is to be thoroughly wiped. If it is an irregular surface, the sample may be obtained by dabbing.

Place the sampling pad or disc in a clean container. Using a permanent marker, identify the sample collection number, date and inspector's initials on the sample container. Place each sample collected in a large polyethylene bag.

Record the surface area type and sample location on the Receipt for Samples, on the incident diagram, and in the investigative notes. Other information recorded on the Receipt for Samples includes the solvent used, the suspected ingredients in the pesticide spray solution and whether the surface sample represents pesticides in concentrate, tank mix or residue from drift or overspray.

Store the samples in the freezer or refrigerator and ship to the laboratory in a manner that maintains the integrity of the sample, following proper chain-of-custody procedures.

GRID PATTERN FOR SURFACE SAMPLING

Grid patterns can be used for surface wipe sampling to establish the extent of contamination. For example, it may necessary to establish that a broadcast carpet treatment occurred when labeling only allowed a baseboard treatment. Grid surface samples can also be taken to establish a drift pattern in or on a structure.

Always collect a control sample prior to any other sampling. At a treatment site, sample from an area of lowest concentration and move in a direction towards the area of highest concentration to prevent contamination of samples. The grid pattern should be in straight lines and all grid points should be an equal distance apart.

Create a diagram of the sampling area. On the diagram, identify the location from which each sample was taken. Include distances from landmarks, such as walls, and distances between samples.

Follow the procedures for taking discrete surface samples, as described above. Each sample represents one point on the grid for that site. Do not composite the samples.

CLOTHING

Collect footwear and clothing only when contamination is suspected. It may be necessary to collect clothing and footwear samples away from the incident site. The applicator or the person(s) who reported the incident may not be found at the incident site.

Should the history of the clothing be unknown, attempt to find out about the integrity of the clothing sample. Ask if the clothing has been washed since the incident. If the clothing has been washed, the inspector should not collect the sample.

Inform the individual who is providing the clothing that the clothing will not be returned.

Wrap each article in aluminum foil prior to placing it into an inverted 18”x 30”, or larger, heavy clear polyethylene bag. Properly knot and seal each bag. Identify and officially seal samples immediately as they are taken.

SAMPLING IN SUPPORT OF RESIDUE AND ENVIRONMENTAL SAMPLING

While conducting residue and environmental sampling the inspector may encounter technical pesticide formulations and tank mixes used during the suspected mis-application that has given rise to the inspection. Samples of these products should be taken to check

for mis-formulation, adulteration, cross-contamination and other potential problems. The results of this sampling and analysis will be relevant to the inspection.

While safety issues are important when conducting residue and environmental sampling, different safety issues may be present when collecting samples of formulations and tank mixes. Therefore, review Chapter 2, "Health and Safety", and any precautionary statements on product labeling prior to collecting the sample.

PESTICIDE FORMULATIONS (TECHNICAL GRADE)

Read and follow all precautionary statements on the label before sampling a formulated pesticide material (i.e., protective clothing and equipment requirements). If a label is not available, wear the maximum safety equipment (respirator, Tyvek suit, coveralls, rubber gloves, rubber boots and goggles).

Chapter 6, "Pesticide Product Sampling", provides guidelines on sampling a pesticide product. However, if possible, collect the entire container with its contents. Smaller samples can always be collected from the larger container.

Sample tools, if re-useable, must be cleaned with hexane or isopropyl alcohol and air dried before collecting additional samples.

Avoid cross-contaminating samples by keeping these samples separate from all other samples (i.e., residue) at all times.

To avoid cross-contamination:

- Liquid bulk samples are to be collected in 8 oz. amber glass bottles with Teflon lined caps.
- Dry bulk samples are to be collected in glass pint or quart containers, or pint or quart size metal paint containers.

Review the pesticide label for storage instructions. Chill the sample to store and ship, unless otherwise stated on the label. Do not allow the sample to freeze.

TANK MIX

Laboratory analysis of tank mix samples will help to identify the active ingredient and any possible contaminants in the tank mixture, or other characteristics of the mixture.

Use 8 or 16 ounce amber glass containers with Teflon-lined lids to collect samples. Do not allow tank mix solutions to contact rubber or plastic as these materials may affect the analytical results. Thoroughly agitate the liquid in the tank before sampling.

Using a clean or decontaminated siphon and bulb suction apparatus, collect a sample from the tank. If the solution is adequately mixed to ensure uniformity, a sample can be collected from

the drain system. Application rigs can be sampled at spray boom nozzles. Following actual application, have the operator loosen boom nozzles and drain the pesticide mix into the sample container. Be sure that the operator tightens the nozzles on the boom after the sample has been taken.

Chill the sample to store and ship. Do not allow the sample to freeze. Do not store or ship tank mix samples with or near foliage or soil samples.

Decontaminate all tools and change or wash gloves to prevent cross-contamination of samples.

SAMPLE STORAGE, PRESERVATION AND SHIPPING

The proper collection, storage and shipping of samples are all critical elements of the sampling process and can affect the analysis results. Steps must be taken early in the sampling process to avoid anything that could compromise the integrity of the sample, such as loss, contamination or tampering.

Ideally, samples should be analyzed as soon as possible after they are collected. In many situations, however, this may not be possible and consideration must then be given to assuring the integrity of the sample by utilizing proper storage, preservation and shipping methods.

STORAGE AND PRESERVATION

If samples must be stored temporarily, it is best to refrigerate or even freeze them to prevent deterioration of the sample and degradation of the chemical. Contact the supervisor or laboratory if in doubt about the specific requirements for storage of a particular kind of sample.

All samples should be stored in an insulated cooler to protect from extreme heat and cold during transit to the laboratory from the time of collection. In extremely hot conditions, it may be necessary to include ice inside the cooler in order to maintain the integrity of the sample. The inspector should read and follow the label statement for storing the samples under or over the listed temperatures.

Table 7-1 summarizes the general requirements for preserving various sample types during storage (i.e., field and laboratory) and shipping to the laboratory. Refer to the specific sample type in the “Sampling Procedures” section of Chapter 6 in this manual for additional information.

TABLE 7-1: SAMPLE PRESERVATION

Sample Type	Container	Field	Storage	Ship
Foliage				
Discrete	PB	C	F	DI
Grid	PB	C	F	DI
Composite	PB	C	F	DI
Dislodgeable	GJ	C	R	WI
Commodity (field, packed)	PB	C	R	WI
Soil				
Discrete (surface)	GJ	C	F	DI
Discrete (known depth)	GJ	C	F	DI
Discrete (furrowed field)	GJ	C	F	DI
Grid	GJ	C	F	DI
Composite	GJ	C	F	DI
Sediment	GJ	C	F	DI
Water	GJ	WI	R	WI
Air	GJ	DI	F	DI
Animals, fish, birds, bees	GJ	C	F	DI
Surface				
Wipe	GJ	C	F	DI
Grid	GJ	C	F	DI
Clothing	PB	C	F	DI
Tank-Mix	GJ	C	R	WI

NOTE: A**ll** sample containers are to be sealed in a plastic bag in the field.

(C) — Chill (wet Ice or freezer pack)
(DI) — Dry Ice
(F) — Freeze
(GJ) — Glass Jar/sealed in Plastic Bag
(R) — Refrigerate
(PB) — Sealed in Plastic Bag
(WI) — Wet Ice

SHIPPING PROCEDURES

Packaging and shipping samples must be done properly, using care to ensure that they remain intact when they arrive at the laboratory. Maintain the chain of custody. Pesticide formulation

samples must be packaged to avoid spillage, leakage or deterioration and the possibility of endangering the safety of persons or the environment. Ship samples in accordance with Department of Transportation (DOT) regulations. See Chapter 6, “Pesticide Product Sampling”, for shipping information.

CHAPTER EIGHT
USE INSPECTIONS

CONTENTS

Statutory Authority 2
Objectives 3
Use Inspections 3
- Health and Safety During a Use Inspection 4
- Inspector Obligations and Procedures 4
- Use Inspection Procedures 4
- Discussions with Owner/Operator/Applicator or Agent in Charge of Property 8

Instructions for Conducting For Cause Use Inspections 9
- Inspector Obligations and Procedures 9
- Reports 11

USE INSPECTIONS

STATUTORY AUTHORITY

FIFRA section 12(a)(2)(G) states, "it shall be unlawful for any person to use any registered pesticide in a manner inconsistent with its labeling."

FIFRA section 2(ee) states that the phrase "to use any registered pesticide in a manner inconsistent with its labeling" means to use a pesticide in a manner not permitted by the labeling. For example, if an inspector finds a person using a pesticide outdoors that is labeled "for indoor use only," the person has used the pesticide "in a manner inconsistent with its labeling" in violation of FIFRA. FIFRA Section 2(ee) does not include:

- Applying a pesticide at a rate, concentration or frequency less than specified on the labeling, unless the labeling specifically prohibits deviation from the specified rate, concentration or frequency.
- Applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable and adverse effect on the environment.
- Employing any method of application not prohibited by the labeling.
- Mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling.
- Any use of a pesticide in conformance with FIFRA sections 5 (Experimental Use Permits), 18 (Exemption of Federal or State Agencies — Emergency Exemption) or 24 (Authority of the States).
- Any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of the Act.

FIFRA section 26 authorizes primary enforcement responsibility to states for pesticide use violations. However, EPA retains pesticide use authority for the advertising related to 40 C.F.R. Part 168.22(b)(5) and Federal Register at 57 FR 19,174, May 28, 1986. See Chapter 4.

OBJECTIVES

The objectives of use inspections are to:

- Determine whether pesticides are being used in accordance with label instructions.
- Collect information about pesticide use and pesticide label and labeling materials.
- Determine compliance with Worker Protection Standards, if pesticides are used in an agricultural setting.

USE INSPECTIONS

In states without primacy, and on federal and tribal lands, EPA conducts (1) a routine inspection program and (2) for cause investigations of reported cases of misuse and suspected pesticide related incidents. Additionally, EPA conducts use inspections where: (1) states have waived their FIFRA section 26 authority; (2) states have not acted in a timely manner (FIFRA section 27); or (3) at the request of states or tribes.

Pesticide use inspections encompass a wide variety of circumstances and inspection sites. The primary focus of a use inspection is to determine whether pesticides are being used properly, in accordance with the pesticide label and applicable Worker Protection Standards. Pesticide use inspections include, but are not limited to, the following locations:

- Agricultural (commercial and private)
    - Field crops
    - Orchards/groves
    - Greenhouses/nurseries
    - Sod farms
    - Forests
    - Vegetable and specialty crops
- Nonagricultural (commercial, public and not-for-hire)
    - Residential sites
    - Structures
    - Rights-of-way
    - Aquatic environments

- Hospitals/nursing homes/clinics
- Veterinary sites
- Lawns, ornamentals and golf courses
- Grain elevators

- Use inspections can be initiated at either the site of application or the applicator's place of business.

Pesticide use activities include storage, handling, mixing/loading, transportation, application and disposal. Use inspections may be performed during any use activity. Use inspections may also occur where pesticides have previously been applied, including inspections at the end of a growing season when the crops are being harvested.

HEALTH AND SAFETY DURING A USE INSPECTION

In addition to the requirements and recommendations contained in Chapter 2 on Health and Safety, at all times during use inspections, the inspector should be aware of biosecurity. See EPA's biosecurity guidance for guidelines to be followed when entering and exiting farms, ranches, etc.

INSPECTOR OBLIGATIONS AND PROCEDURES

Before beginning any federal use inspection, the owner, operator or agent in charge must be issued a written Notice of Use/Misuse Inspection (EPA Form 3540-25; see Exhibit 1-1). The Notice must include the reason for the inspection and whether the inspection is "for cause" or based on a "neutral inspection scheme". If the inspection is "for cause" the Notice must indicate the nature of the suspected violations. The Notice of Use/Misuse Inspection Form contains a "consent" statement that the inspector shall read to the person from whom consent is sought. The form also has a space for the person to sign to provide a written record of the authorization to enter and/or sample based on consent. The absence of a Facility Official's signature on the Notice of Inspection does not invalidate the Notice of Inspection, or establish that consent to the inspection was not provided or that the proper procedures were not followed. See, Chapter 5, "Gaining Entry," for more information.

USE INSPECTION PROCEDURES

Collecting records that document pesticide use is an essential part of every use inspection. Inspectors should obtain records that contradict or corroborate statements regarding pesticide

use. Evidence of any incidents or accidents concerning pesticide use should also be collected. Records collected should be identified as exhibits and attached to the Inspection Report. See, Chapter 16, "Inspection Report and Supporting Documentation," for more information.

Specifically, FIFRA inspectors should gather the following information during a use inspection and then include the information in the Inspection Report:

- **Person interviewed**—Name, address and telephone number.
- **Applicator**—Name, address, telephone number and certification number.
- **Site of application**—Name, address, telephone number; type of business (hospital, aerial applicator, golf course, etc.); crop; area or object treated; target pest; date and time of application; weather at time of application; and any other relevant information.
- **Pesticide applied**—Brand name, EPA Registration Number, EPA Establishment Number, batch number, classification (i.e., general or restricted use) and type of formulation.
- **Rate of application**—Method of application, dilution rate, diluted material applied per unit and actual active per unit.
- **Samples collected** – Physical samples can be taken of formulation, diluted material and residue. It is essential to collect documentary samples as well as physical samples when misuse is suspected. Collect a physical sample of the product if a problem is suspected with product chemistry or where misuse is suspected. Samples may also be collected to substantiate that pesticides were properly mixed and applied. The inspector must give the owner, operator, applicator or agent in charge of the establishment a copy of the completed and signed Receipt for Pesticide Use/Misuse Samples (EPA Form 3540-26; see Exhibit 1-1). For specific sampling procedures, see Chapters 6 "Pesticide Product Sampling" and Chapter 7 "Residue and Environmental Sampling." Types of samples:
    - **Documentary evidence:** Collect documentary evidence when a physical sample of the product is not necessary or available, including those circumstances where no problem with the chemistry of the pesticide is suspected. Documentary evidence consists of anything other than a physical sample (e.g., bin labels or photographs of labels or labeling, advertising, invoices, shipping records or bills of lading, etc.). When collecting a bin label, the inspector must obtain a statement by a company representative that the bin label is/was identical to the label on the product that was sold or distributed as per the sales records.
    - **Physical samples:**
        - **Formulation samples**—If the user is obtaining unusual or adverse results from the use of a product and his/her use is in accordance with label

directions, collect a sample of the commercially packaged pesticide to determine whether it was mis-formulated, contaminated or adulterated. Also collect a formulation sample for each use dilution to verify that problems associated with the use dilution are not related to the pesticide itself. Make a reasonable effort to collect a sample at the user and/or dealer/distributor level. If it is necessary to obtain a sample from a previously opened container, obtain a statement from the user that the product has not been altered (see Chapters 6 and 7 on formulation sampling).

- **Diluted material**—Sample pesticides that are diluted or mixed for use at the user level whenever there is reason to believe that the pesticides may have been diluted or mixed in a manner inconsistent with the label. NOTE: Dilution samples may also be used to show that the diluted pesticide was consistent with the label directions, however, it is best to reserve use of these samples for when it is believed that mixing differs from the label directions or an improper pesticide was selected – since they are often difficult to collect and preserve. Obtain a copy of the registered product's pesticide label to accompany the sample of diluted material. If a photograph of the label and/or an identical label copy cannot be obtained to accompany the sample, hand write the pertinent portions of the label (ingredient statement and applicable dilution/mixing directions) and include them with the sample. If not observed first hand, obtain a statement and/or record copy from the user telling how the material was diluted and mixed. Because the dilution rate may vary with the specifications of the application equipment used, obtain information regarding the type of application equipment used and its calibration. If the pesticide is being applied in accordance with FIFRA section 2(ee) recommendations, document the source of those recommendations with a copy of the recommendations and/or a statement from the applicator.
- **Residue samples**—Residue samples are obtained to determine the residual presence of pesticides on articles. These may include plant materials, animal tissues, soil, drinking water, surfaces, air, runoff water and other inanimate materials. Collect a residue sample when there is reason to believe that a pesticide may have been misapplied.

- **Were the labeling instructions followed?**—Include a thorough review of the label(s) encountered and documentation that the pesticide(s) was/were used as specified by the label. Individual pesticide labels vary greatly, so it is critical that the inspector carefully

document the correct label(s) involved and how the various use directions were followed. Specific areas of pesticide use to be addressed should include but are not limited to the following areas:

- Target pest
- Method and rate of application
- Re-entry interval
- Crop, area, or object treated
- Applicator certification
- Disposal (rinsate/containers)
- Mixing/loading instructions
- Diluent/additives
- Worker Protection Standards
- Protective clothing and equipment
- Precautionary statements
- Environmental precautions
- Transportation/storage
- Pre-harvest intervals
- Spray intervals or application intervals
- Classification
- Relevant weather restrictions
- Endangered species protection restrictions
- Groundwater protection restrictions

- **Records Review**—Review records required to be maintained under federal and/or state regulations, and obtain copies. Determine what records are being maintained by the applicator/firm, review pertinent records and document the pesticide application in question. Pesticide application records for adjoining properties and field history(s) can be used to document pesticide drift. Request a copy of any record that may substantiate violations. Under federal law, applicators are only required to keep records for restricted use pesticide (RUP) use. However, state requirements may specify that all pesticide applicator records be maintained by the applicator.

- **Storage Facility Conditions**—Take note of the types of pesticides in storage (i.e., restricted, canceled, suspended). Inspect the storage area and take note of: (1) any leaking containers; (2) the security of restricted use pesticides; and (3) the proper segregation of pesticide types (for example, rodenticides should be segregated from other pesticides). Check the product label for storage requirements, if any.
- **Worker Protection Standard (agricultural use only)**—The applicability of the Worker Protection Standard should be determined. The regulation governing the Worker Protection Standard is found at 40 C.F.R. Part 170. Inspectors may use the EPA Worker Protection Standard Inspection Manual and the EPA Worker Protection Field Inspection Pocket Guide. Address the following items during the inspection if the Worker Protection Standard applies:
    - Information at the central location
    - Application records
    - Pesticide safety training
    - Decontamination supplies
    - Notice of application and posting of application
    - Early entry requirements
    - Emergency assistance procedures

DISCUSSIONS WITH OWNER/OPERATOR/APPLICATOR OR AGENT IN CHARGE OF PROPERTY

Inspectors should discuss proper pesticide use with the owner/operator, applicator or agent in charge, such as: (1) the existence and purpose of FIFRA; (2) the importance of following label directions; and (3) the need to use pesticides safely, so as to protect human health and the environment by observing all label precautions during all phases of use, including mixing, application, storage, and disposal. If any problems or discrepancies noted during the inspection require immediate corrective action, these problems should be brought to the attention of the applicator or owner/operator so that immediate corrective action may be taken.

The inspector should note in the Inspection Report what was discussed and any voluntary corrective actions. FIFRA inspectors should also report any problems and discrepancies to EPA and should not discuss potential civil or criminal action that EPA may take to address misuse violations with the owner/operator or pesticide applicator.

INSTRUCTIONS FOR CONDUCTING FOR CAUSE USE INSPECTIONS

EPA may conduct a "for cause" pesticide use inspection in response to suspected pesticide misuse incidents or Worker Protection Standard violations to develop the necessary evidence to support a civil or criminal FIFRA enforcement action.

In a "for cause" use inspection, the inspector may be required to visit a number of sites, interview various persons, and collect a number of pesticide samples. The inspector investigating a case of alleged misuse is trying to find and document answers to a number of specific questions. Typical persons that may be questioned include, but are not limited to the following:

- Complainants (i.e., the person who complained of an incident, such as pesticide exposure, drift, injury)
- Physicians/veterinarians
- Pesticide applicators
- Pest control operators
- Pesticide dealers/distributors
- Eye witnesses
- Other federal, state and/or local agencies
- Cooperative Extension operators
- Other experts
- Property owners
- Agricultural employers/employees

INSPECTOR OBLIGATIONS AND PROCEDURES

Due to the potential for harm to humans and the environment posed by pesticide misuse and the need to be responsive to public concern, it is important that the inspector initiate "for cause" inspections as soon as possible. Time is of the essence; the chances of finding pesticide residues in environmental samples can decrease over time.

- The Notice of Inspection – For Use/Misuse inspections use EPA Form 3540-25, see Exhibit 1-1.

- Interview complainant, witnesses, applicator and other parties involved. Take statement(s) using EPA Form 3540-42, see Exhibit 1-1.
- Thoroughly collect and document evidence pertaining to the pesticide use including, but not limited to:
    - Photographs, originals or copies of labels and labeling for pesticides used.
    - Photographs or video tapes showing actual pesticide misuse and/or damage caused by an alleged misuse.
    - Application records and central location information (if involving WPS—refer to WPS guidance).
    - Copies of the applicator certification documents.
    - Statements from the property owner, applicator, owner/operator or witnesses that can attest to the relevant circumstances.
    - Statements from physicians or copies of medical records (may require a medical release).
    - Copies of any available investigation reports completed by other agencies or companies such as state or local agencies or insurance companies.
    - Sketches, diagrams or maps of the area treated and surrounding properties.
    - Samples (physical or documentary).
    - Written recommendations (advisor, consultants, USDA/Cooperative Extension Service bulletins, etc.).
    - State and/or locally required permits and/or notifications.
    - Weather records.
    - Certification/licensing records.
    - Additional labeling (supplemental labels).
    - Regulations/standards.
    - Work order or mix/load sheets.
    - Application records from application(s) to adjoining properties.
    - Employee records (WPS).
- Complete a narrative report of the investigation to include details of the inspection.

REPORTS

Write a narrative inspection report as soon as possible following the completion of the pesticide use/misuse inspection. At a minimum, an inspection report for a suspected use violation should include reference to all information gathered. Include what pesticide was used; where it was applied (site/crop/residential area, etc.); how it was applied (method, dilution rate, application rate, application equipment, safety equipment, etc.); weather conditions (if appropriate); who the suspected responsible party is; and when the pesticide was applied. In addition, include all other relevant information such as consequences of the application (drift, crop damage, illness or injury); explanation of samples, photographs and other evidence collected; and a description of any follow-up that may be warranted. Attach all completed forms and documents gathered during the course of the inspection to the narrative report as exhibits. See, Chapter 16, "Inspection Report and Supporting Documentation" for more information.

CHAPTER NINE
ESTABLISHMENT INSPECTIONS

CONTENTS

Establishment Inspection Objectives 3
Inspection Procedures 4
Scope of Establishment Inspections 4
Pre-Inspection Preparation 4
Entry and Opening Conference 5
Conducting the Inspection 7
Label Review 7
EPA Establishment Number and EPA Registration Number 8
Books and Records 9
Confidential Business Information 10
Sampling 11
Receipt for Samples 11
Statements 12
Closing Conference 12
Preparing the Inspection Report 13
Marketplace Establishment Inspections 13
Additional Information for Marketplace Inspections 14
When to Conduct Marketplace Inspections 14
Places to Inspect 14
What is a "Pool Shooter"? 15
Pesticide Product Review 16
Shipping Records 16
Bulk Repackager Inspections 17
Exhibit 9-1: Producer Establishment Inspection Checklist 19
Exhibit 9-2: Marketplace Inspection Checklist 24
Exhibit 9-3: Format for any Establishment Inspection Report 26
Exhibit 9-4: Conducting the Labeling Review for Producer Establishment Inspections 28
Exhibit 9-5: Books and Records Maintenance and Retention—Producer Establishment Inspection 31
Exhibit 9-6: Pesticide Container-Containment Inspection Checklist 33

Exhibit 9-7: Pesticide Container Inspection Checklist for States with Equivalent Containment Programs....53

ESTABLISHMENT INSPECTIONS

ESTABLISHMENT INSPECTION OBJECTIVES

The objectives of establishment inspections are to:

- Deter and reduce nonompliance by maintaining a strong, timely and active enforcement presence to achieve environmental and human health protection.
- Deter noncompliance by maintaining appropriate levels of compliance monitoring activity, particularly in noncompliant sectors of the regulated community.
- Identify those establishments where a pesticide, device or active ingredient used in producing an end-use pesticide is being produced, or locations where pesticides are being packaged, re-packaged, labeled or re-labeled, to monitor industry compliance with the registration requirements of producing establishments.
- Ensure industry compliance with product registration, formulation, packaging and labeling requirements prior to and during the distribution of pesticides and devices in the channels of trade; and detect and obtain samples of any unregistered, adulterated or misbranded pesticides or devices being distributed or sold.
- Ensure that restricted use pesticides (RUP) are distributed or sold in accordance with FIFRA.
- Ensure that books and records required by FIFRA and the implementing regulations are being prepared, maintained and/or submitted to the Agency, so that EPA can:
    - Identify areas of potential future harm to human health or the environment for purposes of possible suspension, cancellation or enforcement action;
    - Identify the responsible establishment in the event of a recall or stop sale order which may be issued to curtail any adverse effects to human health or the environment;
    - Increase the completeness and effectiveness of EPA recalls of suspended or canceled pesticides;
    - Identify and locate violative batches of pesticides;
    - Identify and locate shipments of violative pesticides and devices;
    - Determine compliance with requirements concerning disposal and storage of pesticides, pesticide containers and pesticide-related wastes (on the label/labeling of the product).
- Collect and develop evidence to support legal actions when violations of FIFRA are found at establishments that produce, distribute and sell pesticides or devices.

- Verify compliance with annual production reporting requirements of section 7 of FIFRA.

Note that EPA maintains a list of active establishments on its website, available at:

https://www.epa.gov/compliance/national-list-active-epa-registered-foreign-and-domestic-pesticide-andor-device-producing

INSPECTION PROCEDURES

Establishment inspections may be conducted at a variety of facilities. For example, an establishment can be the facility of a registrant, pesticide formulator, bulk re-packager, toll manufacturer, importer, broker, shipper, dealer, retailer or distribution center. Note, if an establishment inspection concerns "Restricted Use Pesticides: Dealer and Applicator Records Inspections", also see Chapter 11. If an establishment inspection concerns "Pesticide/Device Import/Export Program", also see Chapter 12. Other information pertinent to establishment inspections can be found in Chapter 1, "General Information," Chapter 2, "Health and Safety," Chapter 5, "Gaining Entry", Chapter 16, "Inspection Reports and Supporting Documentation," Chapter 6, "Pesticide Product Sampling" and Chapter 7, "Residue and Environmental Samples".

SCOPE OF ESTABLISHMENT INSPECTIONS

The scope of the inspection will depend on the type of activities in which the establishment is engaged. For example, the scope of an inspection at a pesticide/device producing establishment will be broader than an inspection at a U. S. Customs and Border Protection (CBP) central examination site or CBP bonded warehouse holding a shipment of an imported pesticide/device. Establishments may be engaged in a combination of activities, including repackaging and/or relabeling, bulk repackaging, retail sale of restricted use pesticides, retail sale of general use pesticides, custom blending, and/or commercial application. The inspector must be familiar with the regulatory requirements that pertain to the particular establishment.

The scope of an inspection, including the number and type of samples to be collected, may be based on the type of establishment and other inspection-specific information gathered during the pre-inspection preparation. Exhibits 9-1 through 9-5 may serve as guides for planning the scope of and completing an establishment inspection.

When collecting samples of pesticides or devices that have been packaged, labeled and released for shipment (PLRS), samples may include pesticides or devices produced by the establishment within the past two years and exists elsewhere in the channels of trade.

PRE-INSPECTION PREPARATION

The quality of an establishment inspection can be enhanced by conducting pre-inspection research to prepare for the inspection:

- Identify the name and address of the establishment and the products produced (by name and EPA Registration Number). Obtain a minimum of two years of data for all pesticide and device production from the EPA FIFRA Section Seven Tracking System (SSTS).
- Obtain copies of all labels, supplemental labels and confidential statements of formula (CSFs) for each pesticide produced at the establishment. Labels are publicly available from OPP's Pesticide Product Labeling System (PPLS). The latest CSF provides information on the source(s) of the technical or manufacturing product(s) the establishment uses to produce the end-use product or other products that are produced at the establishment and are available from the product registration jacket at OPP.

  NOTE: The CSF is CBI and cannot be provided to state or tribal inspectors.
- Review inspection history—state, tribal and EPA inspection files.
- Review enforcement history—state, tribal and EPA enforcement files, including any settlements, notices of warning or stop sale orders.
- Identify EPA Establishment Numbers assigned under section 7, if the site is (or was) a pesticide/device producing establishment, or the EPA company number assigned by EPA if the site is a registrant or manufacture of its registered pesticide products.
- Perform an internet search of the establishment to verify any other addresses that may be associated with the actual physical location and an internet search on the product(s) being inspected and the corporate structure of the facility.
- Verify the registration status of each product produced at the establishment in OPPIN (Office of Pesticide Programs Information Network).

ENTRY AND OPENING CONFERENCE

See Chapter 5, "Gaining Entry." During an opening conference, the inspector should raise the facilities right make a claim of CBI. Additionally, during the opening conference, the inspector must begin obtaining necessary information on the facility to complete the narrative portion of the establishment inspection report. Obtain copies of all documents discussed during the opening conference. This information includes, but is not limited to, the following:

- Confirm the proper business name, site address, mailing address and telephone number(s) of the establishment. If there is a related and/or parent company, include the proper business name(s), site address(es), mailing address(es) and telephone number(s) of all related firms.
- The names and titles of the principal officers, partners or owners of the establishment.

- The person(s) attending the opening conference (complete names, titles and telephone numbers of the responsible officials of the establishment present at the opening conference).
- The number of pesticides registered, produced, sold or distributed by the establishment (including the brand names and EPA Registration Number of the pesticides).[1]
- Supplemental or distributor registration agreements or contracts, contract manufacturing agreements, bulk repackaging agreements – obtain copies of each.
- Authorizations and/or toll repackaging agreements with other businesses regulated under FIFRA.
- Guarantees provided by the establishment or to the establishment, pursuant to section 12(b)(1) of FIFRA.
- Records showing the pesticides distributed or sold by the establishment, sorted by product name, EPA Registration Number (manufacturing/batch codes or lot numbers, if present), and indicating the quantity and date of each sale or distribution. Note that FIFRA defines "distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.

  NOTE: Sales and distribution records may be claimed as CBI and, if so, cannot be provided to state or tribal inspectors, except as provided in Chapter 1 of this Manual.
- Obtain records of pesticides/devices being imported, including the name and address of a contract import broker, if used to broker the product, as well as the name and address of the person the product is being imported to.
- Obtain records of consignees who received the pesticide/devices.
- Obtain records of any exported pesticides/devices including a copy of the Foreign Purchaser Acknowledgment Statement (FPAS) and other records.
- Record all manufacturing use product information, including the name of the product, the EPA Registration Number, EPA Establishment Number and the name and address on the label or container.

Note: Although EPA maintains some of this information in data bases and compliance files, inspectors should go over this information during the inspection to confirm the information that is on file with EPA.

[1] Though the Agency tracks pesticide registrations, the establishment may believe that they have "additional" pesticide products registered with EPA, when in actuality some registrations have been suspended or canceled. The inspector should include this list in the inspection report, and note any discrepancies or differences between the establishment's records and EPA's records.

CONDUCTING THE INSPECTION

Upon completion of the opening conference, the inspection should include label reviews, books and records reviews and sampling. These inspection activities may be conducted in any order depending on the inspector's preference and the facility being inspected.

LABEL REVIEW

Label reviews are used to determine compliance with the required elements identified in 40 C.F.R. 156.10(a). The inspector should collect bin labels or photographs of pesticides or devices packaged, labeled and released for shipment (PLRS). PLRS pesticides or devices include those which may have been produced by the establishment within the past two years and exist elsewhere in the channels of trade. Compliance determinations based on the inspector's label review are the purview of the regional EPA enforcement team (case officer and attorney).

Elements of pesticide product labels:

- Name, brand name or trademark under which product is sold.
- The name and address of the producer, registrant, supplemental registrant, distributor or person for whom the pesticide is produced.
- Net contents.
- EPA Registration Number.
- EPA Establishment Number.
- Ingredient statement totaling 100% of ingredients (active ingredients must be listed by the percentage).
- Precautionary statement (i.e., "Caution," "Warning," "Danger," "Keep out of Reach of Children") as prescribed by 40 C.F.R 156, subpart D.
- Directions for use.
- Disclaimer statement.
- Worker protection directions—if applicable.
- Legibility and typeset (6 point or larger).
- If the use classification is "Restricted Use Pesticide," this statement must appear on the front panel of the pesticide product.
- Any suspected false or misleading statements as described in 40 C.F.R 156.10(a)(5).

If the pesticide product is for agricultural use and subject to the WPS requirements, the label must have the following required WPS statements:

- Specific worker protection statements—40 C.F.R 156, subpart K.
- Application restrictions.

- Product-type identification statements.
- Warning statements using an alternate language commonly spoken and read by workers.
- Restricted-entry statements.
- Personal protective equipment statements.
- Specific container labeling—40 C.F.R 156, subpart H.

NOTE: Copies of the "EPA accepted" label can be obtained from the Pesticide Product Labeling System (PPLS) at: https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1. If PPLS does not have the latest accepted label, the inspector and/or manager should obtain the label from the product registration file. The label obtained from the establishment should be a true, accurate, and complete representation of the label affixed to the immediate container of the PLRS pesticide.

The inspector should document any pesticide labels which are damaged, obscured or illegible. All words, statements, graphic representations, designs or other information required on the label and labeling must be clearly legible to a person with normal vision and must be placed with such conspicuousness (as compared with other words, statements, designs or graphic matter on the label) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The location of the label on the pesticide product package is critical—for example, a label inside a box or beneath a dust cover does not meet the prominence and legibility requirement. Inspectors should document any labeling practices which do not make FIFRA labeling requirements prominent and legible.

When labeling is collected, the inspector should collect a statement from the establishment which states clearly that the label provided to the inspector is the identical label to the label attached to the pesticide/device for distribution and sale. If multiple labels exist for one product, the inspector should clarify which label was associated with which sales/distributions of the product.

Note that the Agency has the authority to take photographs of any pesticide or device being inspected that is labeled and released for shipment in lieu of or in addition to obtaining samples of bin labeling. Take a photograph of all relevant pesticide/device labels and containers. Should management object to the use of cameras in their establishment, the inspector should request that the material to be photographed be moved to a non-sensitive area of the establishment (such as the loading dock).

See Exhibit 9-4 for more information on conducting a label review for a producer establishment inspection.

EPA ESTABLISHMENT NUMBER AND EPA REGISTRATION NUMBER

The EPA Establishment Number (EPA Est. No.) is a facility identifier comprised of a company number, a two letter state or three letter country code, and a number indicating the order of

the establishment registered in a given state or country. For example: EPA Est. No. 80156-NY-002 would indicate the second establishment registered for company number 80156, which is located in the State of New York.

In addition to labeling requirements at 40 C.F.R. Part 156, the establishment number must appear on the product label, or on the immediate container of the product. If the establishment number cannot be seen or clearly read through the wrapping or packaging, it must also appear on the outside container or wrapper of the product. (40 C.F.R 156.10(f)) The establishment number is often grouped together with the EPA Registration Number (EPA Reg. No.), but such placement is not required.

Devices must be produced in registered producing establishments and they must have an EPA Establishment Number on the device or the device's label; however, devices do not require an EPA Registration Number.

Producers may seek approval from the EPA Office of Enforcement and Compliance Assurance (OECA)–Office of Compliance (OC), Washington, D.C., 20460, for various techniques or formats for displaying the establishment number.

The following are examples of approved formats that may be adapted for use by pesticide producers:

EPA Est. No. 123-IN-1, 123-IN-2, 123-MA-1

or

EPA Est. No. 123-IN-1, -2, -MA-1

Where an inspector encounters a label with multiple establishment numbers, the label must indicate which establishment was the producing establishment of the pesticide product or device. For example, a company (registrant number 123) that has three registered establishments (two in Indiana (IN) and one in Massachusetts (MA)), may print all three establishment numbers on the label or immediate container. However, the establishment where the product was produced must be clearly denoted, i.e., with a clear marking such as a saw-cut, notch, arrow or other similar indicator. It must be clear which EPA establishment produced the pesticide product or device.

A producer may add its own code number to identify the actual production site. A statement following the numbers tells the inspector where to look on the container for the actual producing establishment. For example,

"EPA Est. No. 123-IN-1 (a), 123-IN-2 (b), 123-MA-1 (c)
See the last letter on the bottom of the container for actual establishment."

BOOKS AND RECORDS

A books and records inspection is an integral part of every establishment inspection. See Exhibit 9-5. FIFRA section 8(b) authorizes the inspector to have access to and to copy (1) all records showing the delivery, movement or holding of any pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee, or

(2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement or holding of the pesticide or device. Note: Any inspection with respect to any records and information shall not extend to financial data, sales data other than shipment data, pricing data, personnel data and research data (other than that for a registered pesticide or to a pesticide for which an application for registration has been filed).

An inspector should collect documentary evidence which is representative of how the firm maintains its records. This may include photographs and/or photocopies of records of receiving, production, distribution, sales, manufacturing, contract agreements, labeling, etc. The inspector also should photograph products and their container packaging to support a books and records inspection. Typical records reviewed and collected include, but are not limited to:

- Pesticide sales and/or distribution records.
- Shipping records.
- Manifests.
- Invoices.
- Bills of lading.
- Any record that documents the product's production and movement in the channels of trade. This may include the product's name, EPA Registration Number. or other information identifying the product.

Exhibit 9-5 can be used as a tool during a Producer Establishment inspection to ensure all documents that show the production of the pesticide from start to finish are retained by the establishment. The inspector should ask the retention period for each record shown on Exhibit 9-5 to verify the establishment's record keeping procedures match the "Retention Period" column and check each record/document for the required information listed under the record/document name as denoted by "a, b, c."

The inspector should make every effort to collect sufficient evidence of pesticide/device sale and/or distribution records for the products at the establishment. In many situations one year's worth of evidence may be sufficient. Many establishments keep records electronically and can print out or provide pesticide/device sale and/or distribution records on a CD or portable USB (memory stick/thumb drive). FIFRA inspectors have the authority to review electronic records and to request that they be copied and presented in paper form. If paper copies of electronic records cannot be generated at the time of the inspection, the inspector must note on the Receipt for Samples and/or Statement form the records requested to be sent to EPA as a follow-up to the inspection. The inspector shall specify the date by which EPA should receive the requested records. Provide mailing instructions to the establishment.

CONFIDENTIAL BUSINESS INFORMATION

See Chapter 1, "General Information" and Chapter 16, "Inspection Reports and Supporting Documentation." Some records obtained during establishment inspections may be claimed

as FIFRA confidential business information (CBI). If the owner, operator or agent in charge of the establishment declares certain records as FIFRA CBI, the inspector must follow the procedures in Chapter 1 of this Manual.

SAMPLING

See Chapter 6, "Pesticide Product Sampling." Prior to sampling:

- Determine if the owner or operator in charge wants duplicate samples.
- Make a stock survey of all the pesticides/devices in inventory and packaged, labeled and released for shipment into the channels of trade.
- Inspect all technical or manufacturing use chemicals or registered products, to obtain the evidence necessary to determine whether the claims made on the label are in compliance with FIFRA. Collect samples for chemistry analysis, as necessary.

During sampling:

- Collect physical samples only from pesticides/devices that are packaged, labeled and released for shipment.
- As an official sample, inspectors may collect "bin labels" for all pesticides/devices that the producing establishment is or may be producing or are held in inventory or that may have been produced by the establishment within the past two years and may exist elsewhere in the channels of trade.
- As an official sample for all pesticide products used in the manufacturing process, the inspector may collect a documentary sample of the product (photograph of the entire label and entire container). Collect records on how, where and from whom the establishment obtained each product.

RECEIPT FOR SAMPLES

FIFRA section 9(a)(2) requires the inspector to provide to the owner, operator or agent in charge of the establishment a receipt for any samples taken during the inspection, describing the samples obtained and, if requested, to provide a portion of each sample equal in volume or weight to the portion retained. If an analysis of the samples is made, a copy of the results must be provided. Carefully complete a Receipt for Samples (EPA Form 3540-3; Exhibit 1-1), clearly identifying each sample collected by:

- Sample number with subsample, if any. An example of a sample number consists of: (1) the date (mmddyy); (2) the inspector's credential number (3) the inspection sequence (including sample or subsample numbering (A, B, C, or 001, 002, 003)); (4) the inspector's initials. For example, 01/09/2012-17942-123-001-MP
    - 123 = inspection sequence number
    - 001 = sample or subsample number
    - 17942 = inspector credential number

  - 01/09/2012 = date
  - MP = inspector initials

- Quantity of pesticide/device collected from a total quantity of product in inventory.
- Brand name.
- EPA Registration Number.
- EPA Establishment Number.
- Active ingredient.
- Net content.
- Batch codes or lot number(s).
- Name of registrant, producer, supplemental registrant, distributor or person for whom the pesticide/device is produced.

The Receipt for Samples Form must be completed in its entirety and signed by both an establishment representative and the inspector. A copy of the Receipt for Samples must be left with the owner, operator or agent in charge of the establishment.

STATEMENTS

It may be necessary to also obtain a statement during an inspection detailing any facts told to the inspector during the inspection which may be relevant to the inspection and/or documentation, samples, etc. For example, a statement may be a critical piece of evidence to establish that a collected label is identical to the label associated with documented sales. Use Statement Form 3540-42; Exhibit 1-1. The inspector should prepare the statement by printing or scripting very legibly, describing the facts (as heard) or any relevant points that were made to the inspector. Upon completion of the statement, the inspector should ask the owner/operator to read the statement and sign in the appropriate block. If the inspector has made an incorrect statement on the statement form, the inspector should ask the owner/operator to put a line through the statement and initial the location. If the owner/operator refuses to sign the statement, the inspector should note this fact on the statement form or in the operator's signature block and the inspector should initial that block and sign the form in the appropriate inspector signature block. The inspector should retain the original statement form and a leave copy with the owner/operator at the closing conference.

CLOSING CONFERENCE

Always hold a closing conference with the establishment representative(s). The conference can be used to:

- Clarify any outstanding issues found during the inspection.

- Identify any documentation that was not readily available during the inspection that may need to be collected and sent to the EPA-DCO. Items to be provided at a specified later date should also be listed on the Receipt for Samples Form, the statement form or both. A confirmation letter should also be sent to the establishment to reiterate the documents required and the due date for providing the documents.
- Answer any questions and address any concerns that the owner, operator or agent in charge of the establishment may have. The inspector must be careful to answer only those questions that are within his/her knowledge and expertise or direct the establishment representative(s) to appropriate EPA regional personnel on those issues that cannot be readily answered.
- Avoid making any statements regarding compliance status or enforcement.

PREPARING THE INSPECTION REPORT

A narrative report or inspection report must be completed for each establishment inspected. The inspection report should be completed as soon as possible after the inspection. See Chapter 16, "Inspection Reports and Supporting Documentation."

MARKETPLACE ESTABLISHMENT INSPECTIONS

See Exhibit 9-3. In addition to the general objectives of an establishment inspection, the following objectives are relevant for marketplace inspections:

- To detect and obtain samples of any unregistered or misbranded pesticides or devices being sold, distributed or marketed to the public.
- To determine whether restricted-use pesticides are being sold in accordance with FIFRA.
- To review labeling, advertising material, as well as accompanying literature, and other claims to determine whether any false or misleading claims are being made for the product.
- To document and/or review the label and any accompanying literature to determine if the product is an unregistered pesticide or a misbranded pesticide or device.
- To obtain samples of products that were not available for sampling at the producer's establishment.
- To follow-up on recalls, stop sales, suspensions and cancellations.
- To obtain samples of products subject to deterioration.
- To determine whether supplementary FIFRA sections 18 or 24(c) labeling has been provided by registrant/producer.

ADDITIONAL INFORMATION FOR MARKETPLACE INSPECTIONS

Once lawful entry has been gained, the inspector should survey the pesticides and devices being offered for sale as follows:

- Review the labels and/or labeling.
- Inquire whether there are supplemental FIFRA section 18 or 24(c) labels and whether they are provided to those receiving the products. Obtain copies for review.
- If a violation is discovered, collect a sample to support findings.
- If the label violation is serious enough that it may create a hazard, the regional supervisor should be called immediately to discuss the advisability of placing a Stop Sale, Use, or Removal Order (SSURO) on the misbranded or unregistered product. (See Chapter 14, "Stop Sale, Use or Removal Orders" for instructions on issuing SSUROs.)
- If a cancelled or suspended product is encountered, this fact should be brought to the attention of the inspector's supervisor, who will determine the appropriate course of action.

Photographic evidence should be taken whenever appropriate and possible. Voluntary corrective actions should be noted in the inspection report.

WHEN TO CONDUCT MARKETPLACE INSPECTIONS

In general, marketplace inspections should be scheduled by seasonal demands. For example, during the growing season, feed, seed and fertilizer outlets are good sources of agricultural pesticide products. Spring and summer are good seasons to inspect for swimming pool and spa products. During the winter months, urban outlets could be surveyed for household pesticide products. Additionally, such inspections might be triggered at any time by a citizen complaint or tip.

PLACES TO INSPECT

An inspector must always remain alert to the distribution pattern of pesticides/devices in his/her area. Both wholesale and retail distributors should be kept under surveillance to be sure that only registered and properly labeled pesticides and devices are being sold. The following lists some suggested distribution points for inspecting pesticides and devices:

- Animal health and veterinarian suppliers.
- Veterinarians.
- Hardware stores.
- Barber and beauty supply dealers.

- Chemical suppliers.
- Dairy equipment supply dealers.
- Medical and dental suppliers.
- Feed, seed and fertilizer dealers.
- Hotel and restaurant suppliers.
- Janitorial supply dealers.
- Paint dealers.
- Pest control operations.
- Swimming pool, spa and waterbed dealers.
- Retail and wholesale grocers.
- Lawn and garden supply dealers.
- Retail outlets, including “big box stores.”

Additional leads to new sources of unregistered pesticides include the following:

- Dealers (question dealer regarding others in the same business).
- Local newspaper advertisements.
- Trade journals.
- Yellow Pages telephone directories.
- Information from state officials.
- E-commerce (internet samples).
- Pool shooters (see below).
- Marine Supply stores/warehouses.

Note: Antimicrobials, treated articles, pet products, swimming pool and pond products, paints, etc., are excellent products for review in addition to typical farm, home, and garden pesticides.

WHAT IS A “POOL SHOOTER”?

A “pool shooter” is an individual or company who, as part of its business, obtains large bulk quantities of swimming pool chemicals to treat residential and commercial pools. Pool shooters fill their application equipment from bulk container(s) of pesticide, and then apply the pesticide directly to pools or into dispensing or metering equipment for later use by pool staff. In this instance the container on the vehicle of the pool company vehicle is known as a “service container.” Inspectors that encounter pool shooters should pay special attention to container/containment regulations, proper handling and use, and pesticide label directions to ensure that the chemicals are being used properly and that the pesticides used are labeled

properly and registered for use in pools. It should also be noted that although the pool shooter is not considered a producing establishment, if the pool shooter obtains its swimming pool chemicals by a bulk delivery to its facility or by having its own tank truck or other bulk container filled at a distributor facility, the facility from which it obtains its product must be registered as an EPA pesticide producing establishment and must comply with the FIFRA section 7 reporting requirements for this bulk repackaging/product transfer activity. Inspectors should verify the registered status of the pool shooter supplier facility.

PESTICIDE PRODUCT REVIEW

- Note any products requiring child resistant packaging (CRP). CRP requirements are found at 40 C.F.R. Part 157. Whether a particular pesticide must comply with these requirements is determined at registration. The inspector needs to determine if the registration requires compliance with CRP. If the registration requires compliance with CRP, the inspector should check for proper packaging.
- Note and document any canceled/suspended pesticides.
- Observe products for leaking containers.
- Note security/safety of restricted use pesticides in storage.

SHIPPING RECORDS

Inspectors should follow the same procedures for marketplace inspections as for establishment inspections and should collect pesticide/device sale and/or distribution records, including shipping records, manifests and invoices, to document movement in the channels of trade. Document the product back to the distributor and/or producer of the product. Make every effort to document sufficient (one year) sales and distribution records for each suspected violative product. If only computer-generated records are available, these should be collected by the inspector. If actual records are unavailable, document this fact in a statement form signed by the agent-in-charge with an explanation of where the records are and how they can be obtained. Clearly convey the nature of records, the time frame of records and deadlines by which the records must be provided.

In some large chain stores or big-box stores, it may be difficult to obtain records. However, records linking the product back to a distribution center may still be obtained. If the distribution location is not within the region or state, the inspector may need to work closely with an inspector in the other region or state to have that inspector obtain the needed records, tracking back to the production of the product. Ensure that this is documented completely in the inspection report and also in the field notebook.

Once the inspector has obtained records linking the product back to a distribution center, it is then necessary to go to the distribution center to obtain documentation linking the product back to the producing establishment. This may require cooperation with other regions or other states.

BULK REPACKAGER INSPECTIONS

With the growing trend for pesticides to be shipped and held in bulk quantities, inspectors may inspect establishments that handle bulk pesticides. Most bulk establishments handle agricultural herbicides; however, other industries use bulk quantities of chemicals such as sodium hypochlorite and quaternary ammonium disinfectants. In some cases (certain herbicides) a bulk amount could be a very small quantity. In addition to the general objectives of an establishment inspection, the following objectives are relevant for bulk repackager inspections:

- Ensure industry awareness of its obligations for packaging, labeling and recordkeeping.
- Document any potential violations.
- Verify evidence necessary to determine compliance with the container/containment regulations.
- Verify evidence necessary to determine compliance with annual production reporting requirements of section 7 of FIFRA.

If the facility receives bulk quantities of pesticides intended to be dispensed into a customer's spray tank for subsequent use, the inspection should proceed as a marketplace inspection. If the facility receives pesticides in bulk quantities (under contract to the basic registrant) and subsequently repackages the product (without alteration) into other labeled tanks for the purpose of distribution, the inspection should proceed as a producer establishment inspection.

Particular items to check at a bulk site include, but may not be limited to, the following:

- Labels on all bulk storage tanks.
- If the firm is repackaging, verify that there is a manufacturing contract between the firm and the basic registrant that authorizes the firm to repackage the product. Obtain a copy of this record.
- Conduct a label review in accordance with Exhibit 9-4.
- Take samples, as appropriate, in accordance with established procedures in Chapter 6.
- Review sales invoices to verify if transfer is occurring in bulk quantities.
- If any production activities are taking place (i.e., labeling, relabeling, packaging, repackaging, producing, or otherwise changing the container of the pesticide or device) verify that the establishment is registered with EPA and that production reports are accurate.

For berms, pads, and other containment structures:

- Ascertain whether there is information on the construction of the containment(s).

- Check, observe and note in the inspection report the conditions of containment(s). Document any problems with containment(s).
- Conduct a capacity verification for each containment to ensure that it meets the capacity and the regulations at 40 C.F.R. 165.

For containers:

- Visually inspect containers.
- Obtain records for the testing of each refillable container and each container's specific identifying number.
- Obtain records for cleaning and residue removal of each container prior to refilling.
- Obtain records of any containers removed from service.
- Labeling of containers—Does the registrant of the product provide the refiller/repackager with container labels for each product produced/refilled?
- The Compliance Strategy for Containers and Containment, the Pesticide Container Inspection Checklist and Pesticide Container-Containment Inspection Checklist

EXHIBIT 9-1: PRODUCER ESTABLISHMENT INSPECTION CHECKLIST

May be used as an inspection tool.

Firm Inspected: _____

EPA Establishment Number: _____

Authorized Representative: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone Number: _____

Credentials Presented: _____

Notice of Inspection Issued: _____

Reason for Inspection: _____

Violation Suspected: _____

- Names, Titles and Telephone Numbers of Principal Officers, Partners or Owners: _____

  _____

- Related Firms and Addresses of Said Companies: _____

  _____

PESTICIDE/DEVICE LABEL, LABELING AND PACKAGING INSPECTION

Pesticides Packaged, Labeled and Released for Shipment/FIFRA section 9(a)

1. Brand Name(s): _____
2. EPA Registration Number(s): _____
3. Label and Labeling Review/40 C.F.R. 156: _____

Child-Resistant Packaging Requirements for Each Pesticide Product Packaged, Labeled and Released For Shipment/40 C.F.R. 157

1. Criteria Requiring Child-Resistant Packaging: _____
2. Unit Packaging: _____

RECORDS RETENTION REQUIREMENTS FOR PESTICIDE PRODUCTION

Records of Production of Pesticides/40 C.F.R. 169.2(a)

1. Brand Name: _____
2. EPA Registration Number/Experimental-Use Permit Number: _____
3. Amounts Produced per Batch:* _____
4. Batch Identification: _____
5. Length of Retention of Records: _____

Records of Production of Devices/40 C.F.R. 169.2(b)

1. Brand Name: _____
2. Quantities of Device(s) Produced:* _____

Records of Receipt of Pesticides, Devices and Active Ingredients/40 C.F.R. 169.2(c)

1. Brand Name of Pesticide, Device or Common or Chemical Name of Active Ingredient:

   _____

2. Name and Address of Shipper: _____
3. Name of Delivering Carrier: _____
4. Date Received by Establishment: _____
5. Quantities Received: _____
6. Retention of Records: _____

Records of Shipment of Pesticides and Active Ingredient/40 C.F.R. 169.2(d)

1. Brand Name of Pesticide, or Common or Chemical Name of Active Ingredient: _____

   _____

2. Name and Address of Consignee: _____
3. Where the Pesticide Under a FIFRA Section 5 Permit, Section 18 Exemption or section 24(c) Registration is/was Produced: _____

4. Name of Originating Carrier: _____

5. Date Shipped or Delivered for Shipment: _____

6. Quantities Shipped or Delivered for Shipment: _____

7. Retention of Records: _____

Other Records/40 C.F.R. 169.2

1. Inventory Records: _____

2. Copies of All Domestic Advertising of the Restricted Uses of Any Pesticide Registered for Restricted Use: _____

   Retention of Records: _____

3. Copies of Guarantees Given Pursuant to FIFRA section 12(b)(1): _____

   Retention of Records: _____

4. Records on the Method of Disposal, Dates of Disposal, Location of the Disposal Site(s), and the Types and Amounts of Pesticides, Device or Active Ingredients Disposed of by the Producer/Contractor:

   _____

5. FIFRA Records: _____

   Retention of Records: _____

6. RCRA Records: _____

Records Retention Requirements of Child Resistant Packaging/40 C.F.R. 157.36

1. Description of the Packaging for Each Registration: _____

2. Certification Statement for Each Registration: _____

3. Test Data Verification of Child Resistance for Each Registration: _____

4. Records Verifying that the Packaging Meets the Compatibility and Durability Standards: _____

Records Requirements under the Pesticide Export Policy/40 C.F.R. 168, Subpart D

1. Confidential Statement of Formula for Pesticides Not Registered Under FIFRA:* _____

2. Specifications or Directions of the Foreign Purchaser: _____

3. Bilingual Labeling and Other Required Labeling: _____

4. Foreign Purchaser Acknowledgment Statements: _____

5. Establishment/Foreign Purchaser Contracts: _____

RECORDS REPORTING REQUIREMENTS FOR REGISTRANTS/ PESTICIDE PRODUCING ESTABLISHMENTS

1. Application for Amended Registration/40 C.F.R. 152.44: _____

2. Modifications to Registration Not Requiring Amended Applications/40 C.F.R. 152.46: _____

3. Currency of Address of Record and Authorized Agent/40 C.F.R. 152.122: _____

4. Submission of Information Pertaining to Adverse Effects/FIFRA section 6(a)(2), 40 C.F.R. 152.125, and 153, Subpart D: _____

5. Supplemental Distribution/40 C.F.R. 152.132: _____

6. Transfer of Registration(s)/40 C.F.R. 152.135: _____

7. Initial Production Reports/Section 7(c) and 40 C.F.R. 167:* _____

8. Annual Production Reports / Section 7(c) and 40 C.F.R. 167:*_____

9. Notification of Stored Pesticides With Canceled or Suspended Registrations/FIFRA section 6(g): _____

POLICY ON BULK PESTICIDE REPACKAGING

1. Bulk Repackaging/*Contract Bulk Repackaging Agreements*: _____

2. Complete End-Use Labeling/Bulk Containers: _____

3. Complete End-Use Labeling/Mini-Bulk Containers: _____

ADDITIONAL INFORMATION

1. Private Labeling by a Contractor: _____

2. Private Labeling Under Contract for Another Registrant/Distributor: _____

3. Contract Manufacturing Agreements: _____

TECHNICAL OR MANUFACTURING USE PESTICIDES OR CHEMICALS

1. Ensure that products that require registration have the appropriate EPA Registration Number, EPA Establishment Number and proper labeling.

2. Collect invoices, shipping records, bills of lading manifests, and common carrier records that pertain to each technical or manufacturing use product.
3. Collect any contract manufacturing agreements where the establishment is producing a pesticide from another firm, etc. (e.g., supplemental distributor, supplementally registered product, distributor product).

(*) – Note – This is CBI information which can only be viewed by federal inspectors.

EXHIBIT 9-2: MARKETPLACE INSPECTION CHECKLIST

May be used as an inspection tool

Firm Inspected: _____

Authorized Representative: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone Number: _____

Credentials Presented: _____

Notice of Inspection Issued: _____

Reason for Inspection: _____

Violation Suspected: _____

- Names, Titles and Telephone Numbers of Principal Officers, Partners or Owners: _____

  _____

- Related Firms and Site Addresses of Said Companies: _____

  _____

PESTICIDE LABEL, DEVICE LABEL, LABELING, AND PACKAGING INSPECTION

Pesticides Packaged, Labeled and Released for Shipment/FIFRA section 9(a)

1. Brand Name(s): _____
2. EPA Registration Number(s): _____
3. Label and Labeling Review/40 C.F.R. 156: _____

Child-Resistant Packaging Requirements for Each Pesticide Product Packaged, Labeled and Distributed-Sold/40 C.F.R. 157

1. Criteria Requiring Child-Resistant Packaging: _____

2. Unit Packaging: _____

Records of Shipment of Pesticides, Devices and Active Ingredients/40 C.F.R. 169.3

1. Brand Name of Pesticide or Device: _____
2. Name of Originating Carrier: _____
3. Date Shipped or Delivered for Shipment: _____
4. Quantities Shipped or Delivered for Shipment: _____
5. Bill of Lading, shipping records, invoices, etc.: _____

Other Records

1. Copies of All Domestic Advertising of Pesticide/40 C.F.R. 168.22: _____
2. Copies of Guarantees Given Pursuant to FIFRA section 12(b)(1): _____

EXHIBIT 9-3: FORMAT FOR ANY ESTABLISHMENT INSPECTION REPORT

Report on Establishment Inspection to Determine Compliance with FIFRA

Establishment Name
Street Address
[Mailing Address if different]
City, State Zip Code

Date of Inspection
Month Day, Year

Performed by:
U.S. Environmental Protection Agency
Office/Division/Branch
Address
City, State Zip Code
FIFRA Establishment Inspection Report
[Inspection No. 01FIFRA ___]

I. Company Information

A. Company Name
B. Establishment Registration Number
C. Responsible Official
D. Type of Ownership

II. Date of Inspection

III. Participants

A. Company
B. U.S. EPA/State

IV. Objectives

To inspect/investigate ... the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

V. Company Background

VI. Inspection Summary

A. Opening Conference
B. Inspection Observations and Sample Collection
C. Closing Conference

VII. Attachments

A. Establishment Inspection Report Form
B. FIFRA Notice of Inspection
C. FIFRA Receipt for Samples
D. EPA Chain of Custody
E. Statements
F. Labeling
G. Sample Reports of Analysis
H. Photographs
I. Diagrams

(Inspector's Signature) (Date)

(Inspector's Name)

(Title)

EPA region, state or tribal affiliation

EXHIBIT 9-4: CONDUCTING THE LABELING REVIEW FOR PRODUCER ESTABLISHMENT INSPECTIONS

When conducting a producer establishment inspection, a *word-for-word* comparison with the registered label, when available, should be made of all labels being reviewed. The inspector should ascertain compliance with all stipulations of the letter of acceptance.

The inspector may perform label comparisons to "bin" labels. Official *samples may only be collected from the products that are packaged, labeled and released for shipment.* However, a "bin" labeling review can provide a valuable background for follow-up sampling at consignees and obtaining voluntary corrective action at the producer level. Copies of all "bin labels" should be collected as documentary evidence ("DOC") and identified on the Receipt for Samples Form. Additionally, a Statement Form (EPA Form 3540-42), signed by the company official, should be obtained to link the "bin label" to the actual labeled product or specific batches of product previously produced, sold or distributed.

Establishment Inspections (Marketplace, Producer, Dealer, Bulk Facility, etc.)

When conducting a basic label review, the inspector should be aware of labeling requirements and be alert for products that may be violative. The following paragraphs list some of the things an inspector should be aware of:

Product name, brand or trademark.

Name of manufacturer, registrant or person for whom manufactured—If the product is not produced by the registrant, the name must be qualified by "packed for...," "distributed by...," "sold by...," or a similar statement.

EPA Registration Number—The EPA Registration Number may be listed as "EPA Registration No. XXXX-XX," "EPA Reg. No. XXXX-XX," or "EPA Reg. No. XXX-XX-YYYY." (The "YYYY" is the supplemental registrant's company number.)

EPA Establishment Number—The EPA Establishment Number may appear in any location on the label or immediate container; however, it must appear on the outside container or wrapper of the package if the EPA Establishment Number on the immediate container cannot be clearly read through the outside wrapper or container. It must be listed as "EPA Est. XXXX-(state abbreviation)-XX," or "EPA EST NO. XXXX (state abbreviation)-XXX"; EPA Est. XXXX-XXX (foreign abbreviation).

Net content statement—The net contents must be given in units commonly used in the United States (i.e., pounds, ounces, pints, quarts, gallons). Metric units may also be listed. Liquid units must be used if the product is liquid and weight units must be used if the product is solid, semisolid or viscous. Contents must be expressed in terms of the largest unit present.

Ingredient statement—The ingredient statement usually appears on the front panel. The names used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. Ingredients should total 100%. The common name may be used alone if it is well known.

NOTE: The ingredient statements for products containing arsenic must have a substatement giving the percentage of total and water-soluble arsenic, each calculated as elemental arsenic.

Warning or citation statements—The signal words, "Danger," "Warning" or "Caution" and the statement "KEEP OUT OF THE REACH OF CHILDREN" must appear on the front panel of the label. Any substances in quantities highly toxic to humans must bear all of the following on the label: (1) a skull and crossbones; (2) the word "POISON" in red on a contrasting background; and (3) a statement of practical treatment. In addition, the label must contain precautionary statements necessary to prevent injury to humans and the environment.

Directions for use—Directions for using the product must include the following: (1) the site of application; (2) the rate of application; (3) instructions for frequency and timing applications; (4) restrictions and warnings; (5) any other pertinent information necessary for the protection of the public; and (6) target pest.

Legibility of labeling—Product labeling must be clearly legible and easy to read by a person with normal vision. All required label or labeling text shall appear in the English language.

However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text is necessary, all labeling requirements will be applied equally to both the English and other language versions of the labeling.

Statement of use classification—All restricted use products (RUPs) must have the RUP statement on the top center of the label.

If a review of "bin" labels, for which there is no product packaged, labeled, and released for shipment, reveals a discrepancy, it should be brought to the attention of the producer establishment management. Names and addresses of the consignees of the misbranded product should be obtained to follow up the investigation and collect samples of the product.

The inspector should collect labels, samples, and take photographs of all products found with potential violations. The inspector should exercise care in obtaining the proper shipping records such as the sale and distribution records associated with the actual or potential labeling violations.

If the inspector discovers a serious violation that may require immediate action, he/she should call his/her EPA supervisor while still in the vicinity of the establishment to determine what follow-up might be necessary to address the violation.

Accompanying labeling—Copies of accompanying labeling initialed and dated by a responsible company representative should be collected and documented.

When violative labeling is collected, it should be documented with a statement signed by a responsible individual of the firm, which clearly states that relationship of the labeling to the goods including the following:

Description of labeling—Describe briefly each piece of literature by name and also the manner in which the literature was received. State the quantity of such labeling on hand.

Location of labeling—Report the location of each piece of literature and how much each is on hand.

Methods of distribution—Determine how the labeling is distributed (i.e., accompanied product, shipped under separate cover).

Source of Labeling—Was the labeling sent to the dealer by the shipper of the product or was it prepared by the dealer? If received from the shipper of the product, document the shipment of the labeling. If prepared by the dealer, determine whether the producer provided the test.

Instructions to dealer—The manufacturer or shipper sometimes provides sales promotion instructions to the dealer. Obtain copies of such instructions, if available, as well as any verbal instructions on how to use them.

EXHIBIT 9-5: BOOKS AND RECORDS MAINTENANCE AND RETENTION—PRODUCER ESTABLISHMENT INSPECTION

Establishment: _____ Inspection Date: _____

Records/Documents	40 C.F.R.	Maintained?		Retention Period
		Yes	No	
1. Pesticide Production (batch) a. Product name b. EPA reg. no. or EUP no. c. Amount per batch & batch identification number	169.2(a)			2 years
2. Device Production a. Brand name b. Quantity produced	169.2(b)			2 years
3. Receiving a. Brand name of the pesticide or device, or common or chemical name of the active ingredient b. Name and address of shipper c. Name of delivering carrier d. Date received e. Quantities received	169.2(c)			2 years
4. Shipping a. Brand name of the pesticide or device, or common or chemical name of the active ingredient b. Name and address of consignee c. Where the pesticide is produced under an EUP, special exemption or special local need d. Name of originating carrier e. Date shipped or delivered for shipment f. Quantities shipped or delivered for shipment	169.2(d)			2 years
5. Inventory a. Types and amounts of pesticide or active ingredients b. Quantities of device in stock	169.2(e)			replace by current inventory
6. Advertising for RUPs a. Copies of all domestic advertising for RUPs to include any advertising the producer has prepared, including any radio or TV scripts for such products	169.2(f)			2 years
7. Guarantee a. Copies of all guarantees given pursuant to FIFRA §12(a)(2)(C)	169.2(g)			1 year after expiration

8. Export a. Copies of the specification or directions for the foreign purchaser for production of pesticide, device or active ingredient b. Copies of product labels and labeling c. Copies of signed foreign purchase acknowledgement statements d. Copies of instructions provided to foreign purchasers e. Copies of exporter certification f. Identity of coded research products	169.2(h) 168.75(c)(3) 168.85(a)			2 years after expiration of contract
9. Disposal a. Method of disposal b. Dates of disposal c. Location of disposal sites d. Types of pesticides and active ingredient disposed of e. Pesticide container statement f. Deviation from normal practice	169.2(i)			20 years[2]
10. Tests on Humans a. Names and addresses of subject tested b. Dates and types c. Written consent of subjects to test d. Information and instructions given subjects e. Adverse effects	169.2(j)			20 years
11. Research Data a. All raw data, interpretations, evaluations and reports supporting a product registration or tolerance petition	169.2(k)			Permanent while registration is valid & producer is in business
12. Child Safe Packaging a. Description of packaging b. Certification statements c. Test data verification d. Verification of compatibility & durability of package	157.36			as long as registration is in effect

Comments:

Inspector Signature: _____ Date:_____

[2] May be sent to EPA for maintenance after 3 years

PESTICIDE CONTAINER - CONTAINMENT INSPECTION

Inspector Number	Date and Time of Visit:	EPA Establishment Number

Establishment Name	Address *(including Street, City, State, and ZIP code)*
Phone Number	

FACILITY ENTRY CHECKLIST

SCREENING QUESTIONS: IS THE FACILITY SUBJECT TO THE CONTAINER/CONTAINMENT REQUIREMENTS?

A. REFILLABLE CONTAINER REPACKAGING

1. Who must comply? 165.60(b), 165.65(a), 165.67(a), 165.70(a)

- Registrants who distribute or sell a pesticide product directly in refillable containers
- Registrants who distribute or sell a pesticide product to a refiller that is not part of its company
- Refillers that are not registrants

If the facility meets any of the above conditions, in section A.1, the inspector must:

- ***Fill out checklists I, II, and V***
- ***Proceed to section B ("Containment Structures")***
- ***Request records in Recordkeeping section A ("Records for Refillable Container Repackaging")*** ☐☐☐

2. Which pesticides are subject to the requirements? 165.63

All products, other than manufacturing use products, plant-incorporated protectants and certain antimicrobial products which are exempt, are subject to the refillable container repackaging requirements. Antimicrobial products used in swimming pools and closely related sites are subject to a reduced set of the requirements.

3. Are there any exceptions? 165.63(h)

The refillable container repackaging regulations do not apply to:

- transport vehicles that hold pesticides in tanks that are integral parts of the vehicle
- refillable containers for gaseous pesticides
- custom blending.

B. CONTAINMENT STRUCTURES

1. Who must comply 165.80(b)

Facilities that handle agricultural pesticides and are:

- Refilling establishments whose principal business is retail sale
- Custom blenders
- Commercial applicators

If the facility meets any of the above conditions in Section B.1 and the conditions of B.3 below (for secondary containment) and B.4 below (for containment pads), the inspector must:

- ***Fill out checklist VI***
- ***Proceed to Section C***
- ***Request records in Recordkeeping section B ("Recordkeeping for Containment")*** ☐☐☐

2. Stationary containers that are subject 165.81(a) & (b)

Stationary agricultural pesticide containers that hold 500 gallons or more of liquids or 4,000 pounds or more of dry materials in affected facilities must have secondary containment except for:

- Empty containers;
- Containers holding only rinsate or wash water and so labeled;
- Containers holding pesticides which are gaseous at atmospheric temperature and pressure; and
- Containers dedicated to non-pesticide use and so labeled.

3. Pesticide dispensing areas that are subject 165.82(a)

Dispensing areas in affected facilities must have containment pads if:

- Refillable containers of agricultural pesticide are emptied, cleaned or rinsed;
- Agricultural pesticides are dispensed from a stationary containers designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons liquid or 4,000 pounds dry for any purpose;
- Agricultural pesticides are dispensed from a transport vehicle for purposes of refilling a refillable container; or
- Agricultural pesticides are dispensed from any other container for the purpose of refilling a refillable container for sale or distribution.

C. NONREFILLABLE CONTAINERS

1. Who must comply? 165.20(b)

Registrants who distribute or sell a pesticide product in nonrefillable container.

2. Which pesticides are subject to nonrefillable container requirements? 165.23

All of the following products (other than manufacturing use products, plant incorporated protectants and certain antimicrobial products) are subject to the nonrefillable container requirements.

- Products in Toxicity Category I or II are subject to all nonrefillable container requirements.
- Restricted use products are subject to all nonrefillable container requirements.
- Other products (those in Toxicity Category III or IV and that are not restricted use products) must comply only with the basic DOT packaging requirements in 49 CFR 173.24.

Manufacturing use products, plant-incorporated protectants and certain antimicrobial products are exempt.

If the registrant meets only the conditions in section C(1) above, the inspector must:

- ***Fill out checklist IV*** ☐

If the registrant meets the conditions in section C.1 and either one of the first two bullets in section C.2 above, the inspector must:

- ***Fill out checklist III*** ☐
- ***Request records in Recordkeeping section C ("Recordkeeping for Container Design - Nonrefillables")*** ☐

RECORDKEEPING

A. RECORDS FOR REFILLABLE CONTAINER REPACKAGING

1. Recordkeeping - for registrants (who distribute in bulk to "independent" refillers)[1] - 165.65(i)(1), 165.67(h)(2)&(3) Y ☐ N ☐

Has the registrant kept the following records (for each product the facility is refilling) for the current operating year and maintained them for three years:

- residue removal procedure for each product distributed in bulk?
- list of acceptable containers for each product distributed in bulk?
- a written contract with every independent refiller that is repackaging any of these products?

2. Recordkeeping - for refillers - *(both "independent" refillers and registrants who sell or distribute directly in refillable containers) - for each pesticide 165.65(d)(10)&(i)(1), 165.70(e)(10) &(j)(1) Y ☐ N ☐

Has the refiller kept the following records (for each product the facility is refilling) for the current operating year and maintained them for three years:

- residue removal procedure
- list of acceptable containers?

3. Additional requirements for "independent" refillers who are not registrants 165.70(b), (e)(5)(i), (e)(13), (e)(14) & (j)(1)(i) Y ☐ N ☐

- Does the refiller have a written contract from the pesticide's registrant to repackage the registrant's pesticide?

- Did the refiller keep records of the written contract from the registrant for the previous three years? ☐ ☐

4. Recordkeeping - for refillers (both "independent" refillers and registrants who sell or distribute directly in bulk) - each time pesticide is repackaged into refillable containers 165.65(d)(10)&(i)(2), 165.70(e)(10)&(j)(2) Y ☐ N ☐

Does the refiller keep a record of the following, each time a pesticide is repackaged?

- EPA registration number of the pesticide
- the date of repackaging
- serial number or other identifying code of the container. ☐ ☐

Does the refiller maintain records for three years after the date of repackaging?

Refillers of antimicrobial products used in swimming pools and closely related sites are not required to comply with this recordkeeping requirement.

5. Other requirements for refillers (both "independent" refillers and registrants who sell or distribute directly in bulk) 165.65(d)(11)&(12), 165.70(e)(11)&(12) Y ☐ N ☐

Does the refiller maintain records as required by 40 CFR Part 169 (Books and Records of Pesticide Production and Distribution)? ☐ ☐

Does the refiller report as required by 40 CFR Part 167 (Registration of Pesticide and Active Ingredient Producing Establishments; Submission of Pesticide Reports)?

[1] "Independent" refillers are those refillers who are not registrants

B. RECORDKEEPING FOR CONTAINMENT

1. Recordkeeping 165.95

Does the owner/operator maintain the following records for 3 years?

	Y	N
• Name of person conducting inspection or maintenance of containment and date;	☐	☐
• Conditions/deficiencies noted and specific maintenance performed;	☐	☐
• Records of how long non-stationary tanks (with the specified capacities) remain at the facility;	☐	☐
• Record of the construction date of the structure (for as long as the structure is in use and for 3 years afterwards).	☐	☐

C. RECORDKEEPING FOR CONTAINER DESIGN - NONREFILLABLES

3. Recordkeeping 165.27(b)

Does the registrant have records to show compliance with the requirements for:

	Y	N	N/A
• Standard closure	☐	☐	☐
• Container dispensing	☐	☐	☐
• Residue removal	☐	☐	☐

These records do not have to be kept at each production facility, but may be kept at a central location and provided upon request

FACILITY WALKTHROUGH

Producer Establishment and Marketplace

I. CONTAINER DESIGN - Refillable Containers

A. SCOPE AND APPLICABILITY

1. DOT Regulations (for all portable containers) 165.45(a) & (b)

	Y	N
Is the pesticide product a DOT hazardous material?	☐	☐
Does the product comply with the relevant DOT requirements?	☐	☐

- A pesticide product that is not a DOT hazardous material must be packaged in a container that, if portable, is designed, constructed and marked to comply with the requirements of DOT requirements in 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c) & (d), 173.241(c) & (d), Part 178 and Part 180 that are applicable to a Packing Group III material or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. These requirements apply to the pesticide product as it is packaged for transportation in commerce.

- A pesticide product that is a DOT hazardous material must be packaged according to 49 CFR Parts 171-180 as required by DOT or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B.

2. Compliance Date 165.40 (c)

Any pesticide product packaged in a refillable container and released for shipment after ***August 16, 2011*** must be packaged in a refillable container that complies with these requirements.

B. GENERAL REQUIREMENTS

1. Permanent Marking (for all refillable containers) 165.45(d)

	Y	N
Are all refillable containers durably marked with a serial number or other identifying code?	☐	☐

2. One-way valves and tamper-evident devices (for portable containers for liquids) 165.45(e)

	Y	N
Does each opening (other than a vent) of a portable pesticide container designed to hold liquids have a one-way valve, a tamper-evident device, or both?	☐	☐

3. Container integrity (for large stationary containers) 165.45(f)(1)

(The requirements in section B.3 & B.4 apply only to containers designed to hold equal to or greater than 500 gallons of liquid or 4,000 pounds of dry material) AND are located at a refilling establishment of a refiller operating under written contract to a registrant.)

	Y	N
Are stationary containers resistant to extreme changes in temperature and constructed of materials that are adequately thick and that are resistant to corrosion, puncture and cracking?	☐	☐
Are stationary containers capable of withstanding all foreseeable operating stresses?	☐	☐

4. Vent, gauge, and shutoff valve standards (for large containers for liquids) 165.45(f)(2)

Does each stationary liquid container have both:

	Y	N
• a vent designed to relieve excess pressure, prevents losses by evaporation, and excludes precipitation, and	☐	☐
• a shutoff valve, which is capable of being locked?	☐	☐

(External site gauges are prohibited)

II. LABELING - Refillable Containers

A. SCOPE AND APPLICABILITY

1. Who must comply? 156

Registrants must ensure that their labels comply with the revised standards.
Pesticide users must follow the new label directions.

2. Which pesticides must comply? 156

In general, all pesticides must comply with the label instructions in 40 CFR Part 156. However, see the applicability description in each section of the checklist for more details.

3. Compliance Date 156.159

All pesticide products released for shipment after ***August 16, 2010*** must have labels that comply with these requirements.

B. GENERAL REQUIREMENTS

Note: These statements in section B.1-B.4 may be waived or modified on a case-by-case basis by EPA. When the inspector encounters a product with non-standard language, the inspector should check with EPA Office of Pesticide Programs to determine if a waiver or modification was granted.

1. Refilling Statements 156.140(b) and Location of the Information 156.140 Y ☐ N ☐

Is one of the following statements on the label or container?

- "Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose."
- "Refillable container. Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."

These statements must be on the label or the container. If placed on container, they must be durably marked on the container anywhere other than the closure. If placed on the label, the required text, other than the batch code, must be under the heading "Storage and Disposal."

2. Cleaning Instructions 156.144(b) Y ☐ N ☐

Are all cleaning instructions placed under the label heading "Storage and Disposal?"

3. 156.156(a) Y ☐ N ☐

Is one of the following statements found immediately before the cleaning instructions?

- "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."
- "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."

4. 156.156(b)(2) Y ☐ N ☐

Do the instructions for cleaning refillable containers include any of the following?

- The refilling residue removal procedure developed by the registrant;
- Standard industry practices for cleaning refillable containers;
- For pesticides that require dilution prior to application, the following statement:
  "To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times."
- Any other statement the registrant considers appropriate.

III. CONTAINER DESIGN - Nonrefillable Containers

A. SCOPE AND APPLICABILITY

1. Compliance Date 165.20(c)

Any pesticide product packaged in a nonrefillable containers and released for shipment after ***August 16, 2009*** must be in compliance with these requirements.

B. CONTAINER DESIGN STANDARDS

1. DOT regulations 165.25(a) & (b)

	Y	N	N/A
Is the pesticide product a DOT hazardous material?	☐	☐	☐
Does the product comply with the relevant DOT requirements?	☐	☐	

- A pesticide product that is not a DOT hazardous material must be packaged in a container that, if portable, is designed, constructed and marked to comply With the requirements of DOT requirements in 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c) & (d), 173.241(c) & (d), Part 178 and Part 180 that are applicable to a Packing Group III material, or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticides product as it is packaged for transportation in commerce.

- A pesticide product that is a DOT hazardous material must be packaged according to 49 CFR Parts 171-180 as required by DOT, or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B.

2. Standard closures 165.25(d)

	Y	N	N/A
Does the container have one of four specified closures[1]?	☐	☐	☐

- *Applies to liquid agricultural pesticides in containers that are rigid and have capacities equal to or larger than 3 liters (0.79 gallons).*
- *Does not apply to aerosol containers or pressurized containers.*

[1] The four closures identified in the regulations are:
- Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 11.5 threads per inch, National Pipe Straight (NPS) standard;
- Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 5 threads per inch, buttress threads.
- Screw cap, 63 millimeters, at least one thread revolution at 6 threads per inch; and
- Screw cap, 38 millimeters, at least one thread revolution at 6 threads per inch.

IV. LABELING - Nonrefillable Containers

A. SCOPE AND APPLICABILITY

1. Compliance Date 156.159

All pesticide products released for shipment after ***August 16, 2010*** must have labels that comply with the labeling requirements.

B. GENERAL REQUIREMENTS

Note: These statements in section B.1-B.6 may be waived or modified on a case-by-case basis by EPA. When the inspector encounters a product with non-standard language, the inspector should check with EPA Office of Pesticide Programs to determine if a waiver or modification was granted.

40 CFR 156.140(a)(5) lists container types that are exempt from the requirements listed in Section B.2 and B.3 below.[1]

1. Location of the information 156.140

The following statements must be on the label or the container. If placed on container, they must be durably marked on the container anywhere other than the closure. If placed on the label, the required text, other than the batch code, must be under the heading "Storage and Disposal."

2. Identification 156.140(a)(1) Y ☐ N ☐

Is the phrase "Nonrefillable container" on the label or container?

3. Reuse statement 156.140(a)(2) Y ☐ N ☐

Is one of the following statements on the label or container?

Products with labels that allow household/residential use must use (1) or (3):

(1) "Do not reuse or refill this container."

(2) "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."

(3) The following statement may be used if a product is "ready-to-use" and its directions for use allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container."

[1] Pesticide products in the following types of nonrefillable containers, and their packaging, are exempt from the labeling requirements listed above in Sections B.1 and B.2.

- *Aerosol cans*
- *Devices as defined in 40 CFR 152.500 of this chapter*

  A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus or microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.
- *One-time use caulking tubes and other one-time use squeezeable tube containers for paste, gel, or other similar substances*
- *Foil packets for water soluble packaging, repellent wipes, and other one-time use products*
- *One-time use portion control packets, such as polyethylene sleeve packages, or rodenticide placepacks*
- *One-time use bait stations*
- *One-time use cages for repellent or trapping strips*
- *Pet collars or animal ear tags, such as cattle ear tags*
- *One-time use semiochemical dispersion devices*
- *Any container that is destroyed by the use of the product contained*
- *Any container that would be destroyed if reuse of the container were attempted*

	Y	N
4. Recycling or reconditioning statement 156.140(a)(3)		
Is one of the following statements on the label or container?	☐	☐
• "Offer for recycling if available."		
• "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [a pesticide container recycling organization] at [phone number] or [web site]." For example, this statement could be "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council (ACRC) at 1-877-952-2272 (toll free) or *www.acrecycle.org*."		
• A recycling statement approved by EPA and published in an EPA document, such as a Pesticide Registration Notice.		
• An alternative recycling statement that has been reviewed and approved by EPA.		
• "Offer for reconditioning if appropriate."		
5. Batch code 156.140(a)(4)	Y	N
Is there a lot number or other code on the label or container that is used by the registrant or producer to identify the batch of the pesticide product which is distributed or sold?	☐	☐
6. Cleaning instructions 156.144(a) & (c), 156.146		
Other than residential/household pesticides, all pesticides that are dilutable pesticides (liquid or dry) in rigid nonrefillable containers must comply with these standards (cleaning instructions for nonrefillable containers).		
	Y	N
i. 156.144(b)		
Are all cleaning instructions placed under the label heading "Storage and Disposal?"	☐	☐
ii. 156.146(a)		
Does one of the following statements appear on the label immediately before the rinsing instructions?	☐	☐
• "Clean container promptly after emptying."		
• "Triple rinse or pressure rinse container (or equivalent) promptly after emptying."		
• "Triple rinse container (or equivalent) promptly after emptying."		
iii. 156.146(b) & (c)		
The label must include triple rinsing instructions and may include pressure rinsing instructions.		
iv. 156.146(b)		
For liquid dilutable pesticides in containers small enough to shake: "Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."	☐	☐
• ***The statement for solid dilutable pesticides in containers small enough to shake is similar.***		

v. 156.146(b)

For containers that are too large to shake: ☐ ☐

"Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."

vi. 156.146(c)

For liquid dilutable pesticides: ☐ ☐

"Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank to collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

• ***The statement for solid dilutable pesticides is similar.***

This page intentionally left blank

FACILITY WALKTHROUGH

Producer Establishment

V. Refillable Container Repackaging Requirements

A. SCOPE AND APPLICABILITY

1. Compliance Date 165.60(c)

Any pesticide product repackaged into a refillable container and released for shipment after ***August 16, 2011*** must be in compliance with these requirements.

Y	N	N/A
☐	☐	☐

2. Conditions for repackaging by a refiller (that is not the registrant of the product) 165.67(b)&(c), 165.70(b)&(c)

Have the following conditions been met?

A registrant may allow a refiller to repackage its pesticide into refillable containers and to sell or distribute that pesticide if all of these conditions are met:

- The repackaging results in no change in the pesticide formulation.
- One of the following conditions is met:
  - The pesticide is repackaged at an EPA-registered refilling establishment (per §167.20)
  - The pesticide is repackaged by a registered refilling establishment at the site of a user who intends to use or apply the product.
- The registrant has entered into a written contract with the refiller to repackage the pesticide and to use the product's label.
- The pesticide is repackaged only into refillable containers that meet the standards in Subpart C of Part 165.
- The pesticide is labeled and there are no changes to the label other than adding the appropriate net contents and the refiller's EPA establishment number.

B. REGISTRANT RESPONSIBILITIES

1. Develop information: Residue removal and cleaning procedure 165.65(c)(1), 165.67(f)(1)

Has the registrant developed a written residue removal procedure that describes how to clean refillable containers (portable and stationary) before they are refilled?

Y	N
☐	☐

2. Develop information: List of acceptable containers 165.65(c)(2), 165.67(f)(2)

Has the registrant developed a list of acceptable refillable containers (portable and stationary) that can be used to sell or distribute their pesticide?

Y	N
☐	☐

- An acceptable container must meet the refillable container standards and must be compatible with the pesticide.
- Registrants must identify the containers by specifying the container materials of construction and information necessary to confirm compliance with the refillable container requirements.

3. Additional requirements for registrants who distribute or sell pesticides to refillers for repackaging 165.67(b), (d), (g) & (h)(1)

Has the registrant:

	Y	N
• Complied with the conditions for repackaging described in section A.2 above?	☐	☐
• Provided a written contract to the refiller before selling or distributing pesticide to the refiller?	☐	☐
• Provided the residue removal procedure, list of acceptable containers and the pesticide's label before or at the time of distribution or sale of the pesticide to the refiller?	☐	☐
• Kept records of each written contract entered into with a refiller for the current operating year and for three years after that?	☐	☐

C. REFILLER RESPONSIBILITIES

(This section applies to both "independent" refillers and registrants who sell or distribute directly in refillable containers)

	Y	N
1. Establishment Registration 165.65(d)(1), 165.70(e)(1) **Is the refiller's establishment registered with EPA as a producing establishment, as required by 40 CFR 167.20?**	☐	☐
2. Acceptable containers 165.65(d)(3), 165.70(e)(3) **Is the pesticide being repackaged into a refillable container that is identified on the registrant's list of acceptable containers?**	☐	☐
3. Items in possession 165.65(d)(5), 165.70(e)(5) **Does the refiller have the following items prior to repackaging?**	☐	☐
. the label and labeling;		
. the residue removal procedure; and		
. the list of acceptable containers.		
. written contract with the registrant		
4. Inspecting and Cleaning **Can the refiller identify the pesticide previously contained in the container (by looking at the label) to determine if it is necessary to clean the container? 165.65(d)(6), 165.70(e)(6)**	☐	☐
Does the refiller visually inspect the container before repackaging pesticide into it to determine whether the container meets the specified criteria with respect to continued container integrity, required markings and openings? 165.65(d)(7)&(e), 165.70(e)(7)&(f)	☐	☐
Does the refiller clean the refillable container according to the residue removal procedure unless each tamper-evident device and one-way valve (if required) is intact and either of these conditions is met? 165.65(d)(8), (f) & (g), 165.70(e)(8), (g) & (h)	☐	☐
• The refillable container is being refilled with the same pesticide product; or		
• The container previously held a pesticide with a single active ingredient, the container is being used to repackage a pesticide with the same single active ingredient, and there is no change that causes the repackaged pesticide to not meet the product integrity standard.		
If a tamper-evident device or one-way valve is not intact, the refiller must clean the container using the residue removal procedure of the product being repackaged. In addition, other procedures may be necessary to assure that the product's integrity is maintained.		
Note: Antimicrobial products used in swimming pools and closely related sites are not required to comply with the one-way valve/tamper-evident device requirements.		
5. Labeling 165.65(d)(9) & (h), 165.70(e)(9)&(i) **Does the refiller ensure that the pesticide's label is securely attached to the refillable container? The label and labeling must comply with 40 CFR Part 156 and, in particular, the refiller must ensure that the net contents and EPA establishment number appear on the label.**	☐	☐

This page intentionally left blank

FACILITY WALKTHROUGH

Producer Establishment, Custom Blender and Commercial Applicator

VI. Containment Structure Standards

A. SCOPE AND APPLICABILITY

1. **Compliance date 165.80(c)**
   By ***August 17, 2009***, all containment structures must comply with the specific standards applicable to them.

	New	Existing
2. Is the structure new or existing?	☐	☐

Date structure was constructed _____

- **Definition of new structure 165.83(a)**
  A new containment structure is a structure for which installation began after ***November 16, 2006*** if certain conditions regarding permits, construction and contracts are met.
- **Definition of existing structure 165.83(b)**
  An existing containment structure is a structure for which installation began on or before ***November 16, 2006***.

The term "containment structure" refers to both secondary containment and containment pads.

B. GENERAL STANDARDS FOR ALL STRUCTURES

	Secondary Containment		Pads	
	Y	N	Y	N
1. Material 165.85(a) *[NEW]* and 165.87(a) *[EXISTING]*				
• **Is the containment structure constructed of steel, reinforced concrete or other rigid material capable of withstanding the full hydrostatic head and load placed on the structure and compatible with the pesticides stored?**	☐	☐	☐	☐
• **Is the structure liquid-tight with cracks, seams and joints sealed?**	☐	☐	☐	☐
Natural earthen material, unfired clay and asphalt are prohibited.				
	Y	N		
2. Protect appurtenances 165.85(b)(1) *[NEW]* and 165.87(b)(1) *[EXISTING]* **Are appurtenances and containers protected against damage from personnel and moving equipment?**	☐	☐		
	Y	N	Y	N
3. Stormwater control 165.85(b)(3) *[NEW]* and 165.87(b)(3) *[EXISTING]* **Is the containment structure constructed with sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto them from adjacent land or structures?**	☐	☐	☐	☐
4. Configuration of drains 165.85(b)(2) *[NEW]* and 165.87(b)(2) *[EXISTING]*				
[NEW]	Y	N		
• **Are appurtenances, discharge outlets or drains configured so they do not go through the base or wall except for direct connections between containment structures?**	☐	☐		
• **Are appurtenances configured so leaks can be readily observed?**	☐	☐		
[EXISTING]	Y	N		
• **Are appurtenances, discharge outlets or drains through the base or wall sealed, except direct connections between containment structures?**	☐	☐		

C. CAPACITY STANDARDS FOR ALL STRUCTURES

	Y	N
1. Capacity: pads 165.85(c)(3) & (4) *[NEW]* and 165.87(c)(2) & (3) *[EXISTING]* Do all containment pads have one of the following: • a capacity of 750 gallons • 100% of the capacity of the largest container or equipment used on the pad (if no container or equipment on the pad exceeds 750 gallons)?	☐	☐
2. Capacity: liquids 165.85(c)(1) & (2) *[NEW]* and 165.87(c)(1) *[EXISTING]*		
[NEW] Do new secondary containment units have a capacity of 110% (for outdoor) or 100% (for indoor) of the largest stationary pesticide container plus the displaced volume of other tanks and appurtenances?	☐	☐
[EXISTING] Do existing secondary containment units have a capacity of 100% (for indoor or outdoor) of the largest stationary pesticide container plus the displaced volume of other tanks and appurtenances?	☐	☐

D. SPECIFIC STANDARDS FOR ALL LIQUID CONTAINMENT

	Y	N
1. Flotation prevention 165.85(d) *[NEW]* and 165.87(d) *[EXISTING]* Are stationary liquid pesticide containers anchored or elevated to prevent flotation?	☐	☐

E. SPECIFIC STANDARDS FOR ALL PADS

	Y	N
1. Pad design 165.85(e) *[NEW]* and 165.87(e) *[EXISTING]* Do containment pads:		
• intercept leaks and spills?	☐	☐
• have enough surface area to extend under containers on it?	☐	☐
• accommodate at least the portion of the vehicle where the hose or device couples to it, for transport vehicles delivering pesticide?	☐	☐
• allow for removal/recovery of spilled, leaked or discharged material and rainfall?	☐	☐
• have a manually activated pump or an automatic pump with overflow cutoff switches on the receving container?	☐	☐
[FOR NEW PADS ONLY]: • have a surface sloped to a watertight sump or depression?	☐	☐

F. SPECIFIC STANDARDS FOR ALL DRY CONTAINMENT

	Y	N	N/A
1. Containment Design 165.85(f) *[NEW]* and 165.87(f) *[EXISTING]* Are stationary dry pesticide containers:	☐	☐	☐
• protected from wind and precipitation?	☐	☐	☐
• placed on pallets or raised concrete platforms?	☐	☐	☐
• in a storage area that has a floor extending completely beneath the pallets or raised concrete platforms?	☐	☐	☐
• enclosed by a minimum of a 6-inch high curb that extends at least 2 feet beyond the perimeter of the container?	☐	☐	☐

G. STANDARDS FOR ALL CONTAINMENT STRUCTURES

1. Operational 165.90(a)

Does the owner/operator:

	Y	N
• Prevent pesticides from escaping the structure;	☐	☐
• Clean up spills no later than the end of the day of occurrence, except in circumstances where a reasonable delay would significantly reduce the likelihood or severity of adverse effects to human health or the environment;	☐	☐
• Manage spilled and leaked materials according to the label and all regulations;	☐	☐
• Ensure that transfers of pesticides are attended.	☐	☐
• Lock valves on stationary pesticide containers or lock the facility when the facility is unattended, if lockable valves are required? *Lockable valves are required for refillers only.*	☐	☐

2. Inspection 165.90(b)(1)

	Y	N
Does the owner/operator inspect each container, its appurtenances and each containment structure monthly during use?	☐	☐

3. Maintenance 165.90(b)(2) & (3)

	Y	N
• Does the owner/operator initiate repair to any areas showing damage no later than the end of the day on which damage is noticed?	☐	☐
• Does the owner/operator initiate sealing cracks and gaps no later than the end of the day on which damage is noticed?	☐	☐

Repairs must be completed in a time frame that is reasonable taking into account such factors as the weather, and the availability of cleanup materials, trained staff and equipment. Additional pesticides cannot be stored until repairs have been made.

4. Integrated systems 165.92

Containment pads and secondary containment units may be combined as integrated systems if the requirements for each are satisfied.

PESTICIDE CONTAINER INSPECTION

For States with Equivalent Containment Programs

Inspector Number	Date and Time of Visit	Establishment Number

Establishment Name	Address *(including Street, City, State, and ZIP code)*:

Phone Number

FACILITY ENTRY CHECKLIST

SCREENING QUESTIONS: IS THE FACILITY SUBJECT TO THE CONTAINER/CONTAINMENT REQUIREMENTS?

A. REFILLABLE CONTAINER REPACKAGING

1. **Who must comply? 165.60(b), 165.65(a), 165.67(a), 165.70(a)**
   - Registrants who distribute or sell a pesticide product directly in refillable containers
   - Registrants who distribute or sell a pesticide product to a refiller that is not part of its company
   - Refillers that are not registrants

If the facility meets any of the above conditions, in section A.1, the inspector must:

- ***Fill out checklists I, II, and V*** ☐
- ***Proceed to section B ("Nonrefillable Containers")*** ☐
- ***Request records in Recordkeeping section A ("Records for Refillable Container Repackaging")*** ☐

2. **Which pesticides are subject to the requirements? 165.63**
   All products, other than manufacturing use products, plant-incorporated protectants and certain antimicrobial products which are exempt, are subject to the refillable container repackaging requirements. Antimicrobial products used in swimming pools and closely related sites are subject to a reduced set of the requirements.

3. **Are there any exceptions? 165.63(h)**
   The refillable container repackaging regulations do not apply to:
   - transport vehicles that hold pesticides in tanks that are integral parts of the vehicle
   - refillable containers for gaseous pesticides
   - custom blending.

B. NONREFILLABLE CONTAINERS

1. **Who must comply? 165.20(b)**
   Registrants who distribute or sell a pesticide product in nonrefillable container.

2. **Which pesticides are subject to nonrefillable container requirements? 165.23**
   All of the following products (other than manufacturing use products, plant incorporated protectants and certain antimicrobial products) are subject to the nonrefillable container requirements.

   • Products in Toxicity Category I or II are subject to all nonrefillable container requirements.

   • Restricted use products are subject to all nonrefillable container requirements.

   • Other products (those in Toxicity Category III or IV and that are not restricted use products) must comply only with the basic DOT packaging requirements in 49 CFR 173.24.

   Manufacturing use products, plant-incorporated protectants and certain antimicrobial products are exempt.

If the registrant meets only the conditions in section B.1 above, the inspector must:
- ***Fill out checklist IV*** ☐

If the registrant meets the conditions in section B.1 and either one of the first two bullets in section B.2 above, the inspector must:
- ***Fill out checklist III*** ☐
- ***Request records in Recordkeeping section B ("Recordkeeping for Container Design - Nonrefillables")*** ☐

RECORDKEEPING

A. RECORDS FOR REFILLABLE CONTAINER REPACKAGING

Y N

1. Recordkeeping - for registrants (who distribute in bulk to "independent" refillers)[1] - 165.65(i)(1), 165.67(h)(2)&(3) ☐ ☐

Has the registrant kept the following records (for each product the facility is refilling) for the current operating year and maintained them for three years:

- residue removal procedure for each product distributed in bulk?
- list of acceptable containers for each product distributed in bulk?
- a written contract with every independent refiller that is repackaging any of these products?

Y N

2. Recordkeeping - for refillers - *(both "independent" refillers and registrants who sell or distribute directly in refillable containers) - for each pesticide 165.65(d)(10)&(i)(1), 165.70(e)(10) &(j)(1) ☐ ☐

Has the refiller kept the following records (for each product the facility is refilling) for the current operating year and maintained them for three years:

- residue removal procedure
- list of acceptable containers?

Y N

3. Additional requirements for "independent" refillers who are not registrants 165.70(b), (e)(5)(i), (e)(13), (e)(14) & (j)(1)(i)

- Does the refiller have a written contract from the pesticide's registrant to repackage the registrant's pesticide? ☐ ☐
- Did the refiller keep records of the written contract from the registrant for the previous three years? ☐ ☐

Y N

4. Recordkeeping - for refillers (both "independent" refillers and registrants who sell or distribute directly in bulk) - each time pesticide is repackaged into refillable containers 165.65(d)(10)&(i)(2), 165.70(e)(10)&(j)(2) ☐ ☐

Does the refiller keep a record of the following, each time a pesticide is repackaged?

- EPA registration number of the pesticide
- the date of repackaging
- serial number or other identifying code of the container. ☐ ☐

Does the refiller maintain records for three years after the date of repackaging?

Refillers of antimicrobial products used in swimming pools and closely related sites are not required to comply with this recordkeeping requirement.

Y N

5. Other requirements for refillers (both "independent" refillers and registrants who sell or distribute directly in bulk) 165.65(d)(11)&(12), 165.70(e)(11)&(12) ☐ ☐

Does the refiller maintain records as required by 40 CFR Part 169 (Books and Records of Pesticide Production and Distribution)? ☐ ☐

Does the refiller report as required by 40 CFR Part 167 (Registration of Pesticide and Active Ingredient Producing Establishments; Submission of Pesticide Reports)?

[1] "Independent" refillers are those refillers who are not registrants

B. RECORDKEEPING FOR CONTAINER DESIGN - NONREFILLABLES

3. Recordkeeping 165.27(b)

Does the registrant have records to show compliance with the requirements for:	Y	N	N/A
• Standard closure	☐	☐	☐
• Container dispensing	☐	☐	☐
• Residue removal	☐	☐	☐

These records do not have to be kept at each production facility, but may be kept at a central location and provided upon request

FACILITY WALKTHROUGH

Producer Establishment and Marketplace

I. CONTAINER DESIGN - Refillable Containers

A. SCOPE AND APPLICABILITY

1. DOT Regulations (for all portable containers) 165.45(a) & (b)

	Y	N
Is the pesticide product a DOT hazardous material?	☐	☐
Does the product comply with the relevant DOT requirements?	☐	☐

- A pesticide product that is not a DOT hazardous material must be packaged in a container that, if portable, is designed, constructed and marked to comply with the requirements of DOT requirements in 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c) & (d), 173.241(c) & (d), Part 178 and Part 180 that are applicable to a Packing Group III material or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. These requirements apply to the pesticide product as it is packaged for transportation in commerce.

- A pesticide product that is a DOT hazardous material must be packaged according to 49 CFR Parts 171-180 as required by DOT or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B.

2. Compliance Date 165.40 (c)

Any pesticide product packaged in a refillable container and released for shipment after ***August 16, 2011*** must be packaged in a refillable container that complies with these requirements.

B. GENERAL REQUIREMENTS

1. Permanent Marking (for all refillable containers) 165.45(d)

	Y	N
Are all refillable containers durably marked with a serial number or other identifying code?	☐	☐

2. One-way valves and tamper-evident devices (for portable containers for liquids) 165.45(e)

	Y	N
Does each opening (other than a vent) of a portable pesticide container designed to hold liquids have a one-way valve, a tamper-evident device, or both?	☐	☐

3. Container integrity (for large stationary containers) 165.45(f)(1)

(The requirements in section B.3 & B.4 apply only to containers designed to hold equal to or greater than 500 gallons of liquid or 4,000 pounds of dry material) AND are located at a refilling establishment of a refiller operating under written contract to a registrant.)

	Y	N
Are stationary containers resistant to extreme changes in temperature and constructed of materials that are adequately thick and that are resistant to corrosion, puncture and cracking?	☐	☐
Are stationary containers capable of withstanding all foreseeable operating stresses?	☐	☐

4. Vent, gauge, and shutoff valve standards (for large containers for liquids) 165.45(f)(2)

Does each stationary liquid container have both:

	Y	N
• a vent designed to relieve excess pressure, prevents losses by evaporation, and excludes precipitation, and	☐	☐
• a shutoff valve, which is capable of being locked?	☐	☐

(External site gauges are prohibited)

II. LABELING - Refillable Containers

A. SCOPE AND APPLICABILITY

1. Who must comply? 156

Registrants must ensure that their labels comply with the revised standards.
Pesticide users must follow the new label directions.

2. Which pesticides must comply? 156

In general, all pesticides must comply with the label instructions in 40 CFR Part 156. However, see the applicability description in each section of the checklist for more details.

3. Compliance Date 156.159

All pesticide products released for shipment after ***August 16, 2010*** must have labels that comply with these requirements.

B. GENERAL REQUIREMENTS

Note: These statements in section B.1-B.4 may be waived or modified on a case-by-case basis by EPA. When the inspector encounters a product with non-standard language, the inspector should check with EPA Office of Pesticide Programs to determine if a waiver or modification was granted.

1. Refilling Statements 156.140(b) and Location of the Information 156.140 Y ☐ N ☐

Is one of the following statements on the label or container?

- "Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose."
- "Refillable container. Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose."

These statements must be on the label or the container. If placed on container, they must be durably marked on the container anywhere other than the closure. If placed on the label, the required text, other than the batch code, must be under the heading "Storage and Disposal."

2. Cleaning Instructions 156.144(b) Y ☐ N ☐

Are all cleaning instructions placed under the label heading "Storage and Disposal?"

3. 156.156(a) Y ☐ N ☐

Is one of the following statements found immediately before the cleaning instructions?

- "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."
- "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."

4. 156.156(b)(2) Y ☐ N ☐

Do the instructions for cleaning refillable containers include any of the following?

- The refilling residue removal procedure developed by the registrant;
- Standard industry practices for cleaning refillable containers;
- For pesticides that require dilution prior to application, the following statement:
  "To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times."
- Any other statement the registrant considers appropriate.

III. CONTAINER DESIGN - Nonrefillable Containers

A. SCOPE AND APPLICABILITY

1. Compliance Date 165.20(c)

Any pesticide product packaged in a nonrefillable containers and released for shipment after ***August 16, 2009*** must be in compliance with these requirements.

B. CONTAINER DESIGN STANDARDS

1. DOT regulations 165.25(a) & (b)

	Y	N	N/A
Is the pesticide product a DOT hazardous material?	☐	☐	☐
Does the product comply with the relevant DOT requirements?	☐	☐	

- A pesticide product that is not a DOT hazardous material must be packaged in a container that, if portable, is designed, constructed and marked to comply With the requirements of DOT requirements in 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c) & (d), 173.241(c) & (d), Part 178 and Part 180 that are applicable to a Packing Group III material, or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticides product as it is packaged for transportation in commerce.

- A pesticide product that is a DOT hazardous material must be packaged according to 49 CFR Parts 171-180 as required by DOT, or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B.

2. Standard closures 165.25(d)

	Y	N	N/A
Does the container have one of four specified closures[1]?	☐	☐	☐

- *Applies to liquid agricultural pesticides in containers that are rigid and have capacities equal to or larger than 3 liters (0.79 gallons).*
- *Does not apply to aerosol containers or pressurized containers.*

[1] The four closures identified in the regulations are:
- Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 11.5 threads per inch, National Pipe Straight (NPS) standard;
- Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 5 threads per inch, buttress threads.
- Screw cap, 63 millimeters, at least one thread revolution at 6 threads per inch; and
- Screw cap, 38 millimeters, at least one thread revolution at 6 threads per inch.

IV. LABELING - Nonrefillable Containers

A. SCOPE AND APPLICABILITY

1. Compliance Date 156.159

All pesticide products released for shipment after ***August 16, 2010*** must have labels that comply with the labeling requirements.

B. GENERAL REQUIREMENTS

Note: These statements in section B.1-B.6 may be waived or modified on a case-by-case basis by EPA. When the inspector encounters a product with non-standard language, the inspector should check with EPA Office of Pesticide Programs to determine if a waiver or modification was granted.

40 CFR 156.140(a)(5) lists container types that are exempt from the requirements listed in Section B.2 and B.3 below.[1]

1. Location of the information 156.140

The following statements must be on the label or the container. If placed on container, they must be durably marked on the container anywhere other than the closure. If placed on the label, the required text, other than the batch code, must be under the heading "Storage and Disposal."

2. Identification 156.140(a)(1) Y ☐ N ☐

Is the phrase "Nonrefillable container" on the label or container?

3. Reuse statement 156.140(a)(2) Y ☐ N ☐

Is one of the following statements on the label or container?

Products with labels that allow household/residential use must use (1) or (3):

(1) "Do not reuse or refill this container."

(2) "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."

(3) The following statement may be used if a product is "ready-to-use" and its directions for use allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container."

[1] Pesticide products in the following types of nonrefillable containers, and their packaging, are exempt from the labeling requirements listed above in Sections B.1 and B.2.

- *Aerosol cans*
- *Devices as defined in 40 CFR 152.500 of this chapter*

  A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus or microorganism on or in living man or living animals) but not including equipment used for the application of pesticides (such as tamper-resistant bait boxes for rodenticides) when sold separately therefrom.
- *One-time use caulking tubes and other one-time use squeezeable tube containers for paste, gel, or other similar substances*
- *Foil packets for water soluble packaging, repellent wipes, and other one-time use products*
- *One-time use portion control packets, such as polyethylene sleeve packages, or rodenticide placepacks*
- *One-time use bait stations*
- *One-time use cages for repellent or trapping strips*
- *Pet collars or animal ear tags, such as cattle ear tags*
- *One-time use semiochemical dispersion devices*
- *Any container that is destroyed by the use of the product contained*
- *Any container that would be destroyed if reuse of the container were attempted*

4. Recycling or reconditioning statement 156.140(a)(3) Y ☐ N ☐

Is one of the following statements on the label or container?

- "Offer for recycling if available."
- "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [a pesticide container recycling organization] at [phone number] or [web site]." For example, this statement could be "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council (ACRC) at 1-877-952-2272 (toll free) or *www.acrecycle.org*."
- A recycling statement approved by EPA and published in an EPA document, such as a Pesticide Registration Notice.
- An alternative recycling statement that has been reviewed and approved by EPA.
- "Offer for reconditioning if appropriate."

5. Batch code 156.140(a)(4) Y ☐ N ☐

Is there a lot number or other code on the label or container that is used by the registrant or producer to identify the batch of the pesticide product which is distributed or sold?

6. Cleaning instructions 156.144(a) & (c), 156.146

Other than residential/household pesticides, all pesticides that are dilutable pesticides (liquid or dry) in rigid nonrefillable containers must comply with these standards (cleaning instructions for nonrefillable containers).

i. 156.144(b) Y ☐ N ☐

Are all cleaning instructions placed under the label heading "Storage and Disposal?"

ii. 156.146(a) ☐ ☐

Does one of the following statements appear on the label immediately before the rinsing instructions?

- "Clean container promptly after emptying."
- "Triple rinse or pressure rinse container (or equivalent) promptly after emptying."
- "Triple rinse container (or equivalent) promptly after emptying."

iii. 156.146(b) & (c)

The label must include triple rinsing instructions and may include pressure rinsing instructions.

iv. 156.146(b) ☐ ☐

For liquid dilutable pesticides in containers small enough to shake:

"Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

- ***The statement for solid dilutable pesticides in containers small enough to shake is similar.***

v. 156.146(b)

For containers that are too large to shake: ☐ ☐

"Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."

vi. 156.146(c)

For liquid dilutable pesticides: ☐ ☐

"Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank to collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

• ***The statement for solid dilutable pesticides is similar.***

This page intentionally left blank

FACILITY WALKTHROUGH

Producer Establishment

C. REFILLER RESPONSIBILITIES

(This section applies to both "independent" refillers and registrants who sell or distribute directly in refillable containers)

	Y	N
1. Establishment Registration 165.65(d)(1), 165.70(e)(1) **Is the refiller's establishment registered with EPA as a producing establishment, as required by 40 CFR 167.20?**	☐	☐
2. Acceptable containers 165.65(d)(3), 165.70(e)(3) **Is the pesticide being repackaged into a refillable container that is identified on the registrant's list of acceptable containers?**	☐	☐
3. Items in possession 165.65(d)(5), 165.70(e)(5) **Does the refiller have the following items prior to repackaging?**	☐	☐
. the label and labeling;		
. the residue removal procedure; and		
. the list of acceptable containers.		
. written contract with the registrant		
4. Inspecting and Cleaning **Can the refiller identify the pesticide previously contained in the container (by looking at the label) to determine if it is necessary to clean the container? 165.65(d)(6), 165.70(e)(6)**	☐	☐
Does the refiller visually inspect the container before repackaging pesticide into it to determine whether the container meets the specified criteria with respect to continued container integrity, required markings and openings? 165.65(d)(7)&(e), 165.70(e)(7)&(f)	☐	☐
Does the refiller clean the refillable container according to the residue removal procedure unless each tamper-evident device and one-way valve (if required) is intact and either of these conditions is met? 165.65(d)(8), (f) & (g), 165.70(e)(8), (g) & (h)	☐	☐
• The refillable container is being refilled with the same pesticide product; or		
• The container previously held a pesticide with a single active ingredient, the container is being used to repackage a pesticide with the same single active ingredient, and there is no change that causes the repackaged pesticide to not meet the product integrity standard.		
If a tamper-evident device or one-way valve is not intact, the refiller must clean the container using the residue removal procedure of the product being repackaged. In addition, other procedures may be necessary to assure that the product's integrity is maintained.		
Note: Antimicrobial products used in swimming pools and closely related sites are not required to comply with the one-way valve/tamper-evident device requirements.		
5. Labeling 165.65(d)(9) & (h), 165.70(e)(9)&(i) **Does the refiller ensure that the pesticide's label is securely attached to the refillable container? The label and labeling must comply with 40 CFR Part 156 and, in particular, the refiller must ensure that the net contents and EPA establishment number appear on the label.**	☐	☐

CHAPTER TEN
EXPERIMENTAL USE PERMIT INSPECTIONS

CONTENTS

Authority 2
Regional EUP Inspection Program 2
Conducting the EUP Inspection 3
Adverse Effects 5
Inspection Report 5

EXPERIMENTAL USE PERMIT INSPECTIONS

AUTHORITY

FIFRA section 12(a)(2)(H) makes it unlawful for any person to use any pesticide that is under an experimental use permit (EUP) contrary to the provisions of such permit.

FIFRA section 5 authorizes the Administrator to grant an application for a EUP when it has been determined that the applicant needs such a permit in order to accumulate information necessary to register a pesticide. Regulations governing EUPs are found in 40 C.F.R. Part 172.

FIFRA section 5(c) states that use of a pesticide under an EUP shall be under the supervision of the Administrator and subject to the terms, conditions and periods of time prescribed in the permit. The permit will authorize EUP inspections.

FIFRA section 5(e) authorizes the Administrator to revoke any EUP, at any time, if he/she finds that the terms or conditions of the permit are being violated or that the terms or conditions are inadequate to avoid unreasonable adverse effects on the environment as that term is defined by FIFRA.

The Office of Pesticide Programs (OPP), Registration Divisions (Antimicrobial Division, Biopesticides and Pollution Prevention Division, and the Registration Division) review EUP applications and issue the EUP permit. OPP also has the authority to modify or revoke an EUP permit.

OPP will furnish a copy of each EUP, the accepted label, names of the participants, and terms of the program to the region where the pesticide testing will occur.

A state may issue EUPs (40 C.F.R. §§172.20 through 172.26). However, tribes may not issue EUPs.

REGIONAL EUP INSPECTION PROGRAM

The objectives of FIFRA section 5 inspections are to (1) determine whether the terms and conditions of the permit are adequate to avoid unreasonable adverse effects on the environment and (2) determine whether the terms and conditions of the permit are being met. Each regional office is responsible for the supervision of the experimental uses conducted in its region. State agencies participating in cooperative enforcement agreements may conduct EUP inspections on behalf of EPA consistent with the procedures in this Manual. Procedures will be the same as for EPA unless modified by grant agreements or regional policy.

Each regional office will establish its own inspection schedule based on the following list of priorities:

- EUPs for pesticides that are completely new classes of compounds (e.g., juvenile hormones).
- EUPs for chemicals with special potential hazards to humans or the environment, such as:
    - Highly toxic products.
    - Products with propensity to drift.
    - Products with high terrestrial or aquatic mobility.
    - Products of a particularly persistent nature.
- EUPs for chemicals with previously registered uses that were subject to adverse action by EPA.
- EUPs for chemicals manufactured by companies that have a history of noncompliance, inadequate supervision or other indications of problems.
- EUPs for those chemicals that may potentially have a widespread major use (e.g., chemicals that will replace a major pesticide that has been canceled by the Agency).
- Any other EUPs for which OPP or OECA has requested special information or monitoring.

CONDUCTING THE EUP INSPECTION

The inspector must obtain and review a copy of the specific EUP and its accepted label. Specifically, the inspector should ensure that all unregistered pesticides, shipped or used as part of a EUP, have a label with the following elements:

- The prominent statement, “For Experimental Use Only”;
- The Experimental Use Permit number;
- The statement, “Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program”;
- The name, brand or trademark;
- The name and address of the permittee, producer or registrant;
- The net contents;
- An ingredient statement;
- Warning or caution statements;

- Any appropriate limitations on entry of persons into treated areas;
- The EPA Establishment Number, except in those cases where application of the pesticide is made solely by the producer; and
- The directions for use, except that the Administrator may approve the use of the experimental program as labeling provided that such program is to be distributed with the product.

If a registered pesticide is shipped or used as part of an EUP, the product should either bear the EPA accepted label, or a supplemental label that EPA approved specifically for use in the EUP. Inspectors should document the pesticide labels and include in the inspection report both the EPA accepted labels and the labels in use at the EUP site, so EPA can verify that the permit holder is in compliance with FIFRA.

In addition, the FIFRA inspector should verify that the EUP terms, such as the total acreage and use site, match the actual acreage and use site of the EUP. Any variation between what the EUP allows and what is occurring at the EUP site may be a FIFRA violation and should be documented in the inspection report.

The following items must be checked for compliance with the EUP provisions in addition to any specific instructions issued by the regional office:

- The pesticide label and labeling in use at the EUP site must be the same as the EUP accepted label and labeling (see above for the required elements of an EUP label).
- The products must be applied in accordance with the EUP accepted label directions and precautions, and within the terms of the permit.
- If testing activities are taking place, such activities must be supervised by a representative of the permittee.
- The inspector should check for evidence of adverse effects (e.g., worker complaints, signs of plant/crop damage from the application of non-herbicides, etc. See list below.).
- If evidence of adverse effects is observed, the inspector should ask for documentation to prove that EPA headquarters has been notified of this adverse effect.
- The amount of pesticide sold or provided must be consistent with the amount in the EUP.
- The quantities of product shipped and/or received must be consistent with the quantities in the EUP and the shipments must have been made to designated participants only.
- Food or feed that is not covered by a tolerance must be disposed of in accordance with the EUP.

- Unused pesticide must be disposed of in accordance with EUP instructions.

In certain instances, follow-up inspections may be required to verify crop rotation, crop destruction, grazing restrictions, etc.

ADVERSE EFFECTS

The following adverse effects must be documented and reported to EPA:

- Accidents observed or claimed.
- Non-target animal or bee kills (domestic or wild).
- Phytotoxicity to non-target plants (in or out of the target site).
- Unique problems with handling, preparing, mixing or applying the pesticide.
- Other complaints.

INSPECTION REPORT

See Chapter 16, "Inspection Reports and Supporting Documentation." If follow-up inspections are required to verify crop rotation, crop destruction, grazing restrictions, or other practices, the inspector should note this in the report and submit additional reports for each follow-up inspection.

The inspector should document any discrepancies between the EUP terms and the actual conditions of the EUP site and include evidence of any potential violation (such as photographs, statements, documentation and samples) in the inspection report. Since EUPs may involve experimental and/or toxic products, the inspector must immediately report any suspected violation to the EPA regional office and should expedite the preparation of the EUP inspection report.

The inspector must submit a written report to EPA where the inspection was conducted by the state.

CHAPTER ELEVEN
RESTRICTED-USE PESTICIDES: DEALER AND APPLICATOR RECORDS INSPECTIONS

CONTENTS

Statutory Authority 2
Objectives 2
Inspection Procedures 3
RUP Dealer Inspection 3
RUP Applicator Inspection 4

RESTRICTED-USE PESTICIDES: DEALER AND APPLICATOR RECORDS INSPECTIONS

STATUTORY AUTHORITY

FIFRA section 11 and 40 C.F.R. Part 171 (see, in particular, 171.11(g)) require dealers and commercial applicators to maintain records of sales, distribution and application of restricted-use pesticides (RUPs).

FIFRA section 8(b) states that any producer, distributor, carrier or dealer shall furnish, upon request of any officer or employee of EPA, all records showing the delivery, movement or holding of pesticides.

FIFRA section 12(a)(2)(F) states that it shall be unlawful for any person to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with FIFRA section 3(d) and any regulation thereunder, except that it shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator.

OBJECTIVES

The restricted use pesticide (RUP) classification restricts a product, or its uses, to use by a certified pesticide applicator or under the direct supervision of a certified applicator. Because RUPs may be applied only by or under the direct supervision of trained and certified applicators, inspectors should review Chapter 8, "Use Inspections," and Chapter 9, "Establishment Inspections" to become familiar with records maintained by retail dealers and commercial applicators that distribute and/or use RUPs. When inspecting facilities that use, produce, sell or distribute RUPs, the inspector should review these records to establish:

- Compliance with FIFRA record keeping requirements regarding sales, distribution and application of RUPs.
- That RUPs are sold only to certified applicators or non-certified persons for application by a certified applicator who is specifically certified for the use of the particular RUP.

This chapter provides direction for inspections conducted under federal authority in states and in Indian country. Under 40 C.F.R. Part 171, EPA may approve state and tribal plans for certification of applicators of restricted use pesticides. Federal inspectors can, under the

authority of FIFRA section 8(b), conduct dealer record inspections in states and Indian country that have EPA-approved plans for the certification of RUP applicators under 40 C.F.R. Part 171. Since many state and tribal pesticide laws and regulations, including those pertaining to record keeping, may be more extensive than federal requirements, federal inspectors should familiarize themselves with the state or tribe's pesticide laws and regulations prior to conducting these inspections. In cases where state or tribal violations are documented, the inspection file and inspection report must be forwarded to the respective state or tribe for follow-up and/or or enforcement action.

INSPECTION PROCEDURES

The inspector should follow the procedures outlined in Chapter 8, "Use Inspections," and Chapter 9, "Establishment Inspections".

Review records to determine compliance with FIFRA and to ascertain whether all the required information is being maintained. Document any deficiencies (e.g., through photocopies, photographs, statements).

RUP DEALER INSPECTION

Under 40 C.F.R. § 171.11(g), every retail dealer of RUPs in states or Indian country where EPA conducts the applicator certification and training program must report to EPA the dealer's business name and the name and address of each of its dealerships. The dealer must submit revisions to this report as necessary. The inspector should check for evidence to establish compliance with this requirement. The inspector should also note and record any state dealer license held and its expiration date. A dealer that makes RUPs available to a certified applicator or an uncertified person must keep a record of each transaction. A dealer that is also an applicator of restricted-use pesticides must comply with the record keeping requirements that pertain to applicators.

RUP dealers are required to maintain two primary types of sales records which are subject to Agency review: (1) sales to certified applicators and (2) sales to uncertified persons.

For sales to certified applicators, records of each transaction must be retained for 24 months and must include the following information:

- Name and address of each certified person to whom the pesticide was made available for use.
- Certified applicator's certification number, expiration date, certification categories and name of state or other governmental unit issuing the certificate.
- Product name, EPA Registration Number and state Special Local Need Registration Number (if any) on the pesticide label.

- Amount of the pesticide sold and made available for use in the transaction.
- Date of the transaction.

For sales to uncertified persons, records of each transaction must be retained for 24 months and must include the following information:

- Name and address of the uncertified person to whom the pesticide was made available for use by a certified applicator.
- Name and address of the certified person who will use the restricted-use pesticide.
- Certified applicator's certification number, expiration date, certification categories and name of state or other governmental unit issuing the certificate.
- Product name, EPA Registration Number and state Special Local Need Registration Number (if any) on the label of the pesticide.
- Amount of pesticide sold and made available for use in the transaction.
- Date of the transaction.

RUP dealers' stocks should be inspected and RUPs inventoried. The inspector should document the following situations:

- Sales to non-certified persons or for use by non-certified persons.
- Discrepancies between physical inventories and the amount of product documented in transactions (determined by a books and records inspection including computer inventories).
- Improperly labeled products, including agricultural pesticides lacking worker protection label statements.
- Suspended or canceled products sold and/or held for sale and distribution.
- Damaged products and any corrective actions taken.
- Improperly stored products.

RUP APPLICATOR INSPECTION

In any state or Indian country that does not have an EPA-approved certification plan, anyone who uses or supervises the use of any RUP must be certified by EPA. The inspector should check the certified applicator's certification number, certification categories and expiration date.

Commercial applicators and those who contract with commercial applicators to apply RUPs to property owned by another person must maintain applicator records for at least 24 months from the date of pesticide use. Records should include the following information (40 C.F.R. §171.11(c)(7)):

- Name and address of the person for whom the pesticide was applied.
- Location of the pesticide application.
- Target pests.
- Specific crop or commodity and site to which the pesticide was applied.
- Date and time of application.
- Product/trade name and EPA Registration Number of the pesticide applied.
- Amount of pesticide applied and percentage of active ingredient per unit of pesticide used.
- Disposal information.

Pesticide stocks should be inspected and RUPs inventoried. The inspector should document the following occurrences:

- Discrepancies between physical inventories and amount used (determined by a books and records inspection including computer inventories).
- Improperly labeled products, including agricultural pesticides lacking worker protection label statements.
- Suspended or canceled products being held for use.
- Damaged products and any corrective actions taken.
- Improperly stored products.
- Improper disposal of container, excess pesticide or rinsate.
- Application of an RUP outside a category for which the applicator is certified.

CHAPTER TWELVE

PESTICIDE/DEVICE IMPORT AND EXPORT INSPECTIONS

CONTENTS

Authority 2
Exports 2
Export of EPA Registered Pesticides 2
Export of Unregistered Pesticides 3
Inspection and Sampling 3
Procedures 3
Pre-Inspection Activities (Regional Office Function) 4
On-Site Inspection Activities (Regional/State Function) 5
Imports 6
Automated Commercial Environment / International Trade Data System (ACE/ITDS) 6
Import of Unregistered Pesticides 7
Import of Research & Development Pesticides 7
Import of Registered Pesticides and Devices 7
Foreign-Trade Zones 8
Regional Office 8
Inspections and Sampling 10
Import Sampling 10
Inspection without Sampling 11
EPA Regional Office Procedure after Inspection 11
Exhibit 12-1: FIFRA Export Inspection Checklist 13
Exhibit 12-2: FIFRA Import Inspection Checklist 16
Exhibit 12-3: Model Release Notice 18
Exhibit 12-4: Model Notice of Refusal of Admission 19
Exhibit 12-5: Model Notice of Detention and Hearing 21

PESTICIDE/DEVICE IMPORT AND EXPORT INSPECTIONS

AUTHORITY

FIFRA section 17 governs the importation and exportation of pesticides and devices. Sections 17(a) and 17(b) govern pesticides and devices intended for export and notifications to foreign governments. Section 17(c) governs the importation of pesticides and devices.

See FIFRA section 17 and 40 C.F.R. Part 168, Subpart D (Export Policy and Procedures for Exporting Unregistered Pesticides). Additionally, see 19 C.F.R. 12.110 - 12.117 (U.S. Customs and Border Protection (CBP) regulations pertaining to import of pesticides and devices).

EXPORTS

Pesticides may be exported from the United States whether they are registered, unregistered, canceled or suspended—provided certain criteria are met. For example, all pesticides, devices or active ingredients intended for export are subject to the labeling requirements of FIFRA regulations at 40 C.F.R. Part 156. In addition, certain label items must be in both the English language and in the language of the importing country, if English is not the predominantly spoken language or the language used in conducting official business in the importing country. Examples of these label items are the warning, caution, ingredient and practical treatment (first aid) statements; and the word “poison” when it is required on the label.

For the purposes of regulating the exportation of pesticides, the export regulations at 40 C.F.R. Part 168, Subpart D, divide exported pesticides into categories, as outlined below, with differing requirements for each category. For information on labeling requirements for exported pesticides, see PR Notice 99-1 and the Export Policy.

EXPORT OF EPA REGISTERED PESTICIDES

EPA registered pesticides must be exported with EPA approved labels and must bear labeling in both the English language and in the language of the importing country, if English is not the predominantly spoken language, or the language used in conducting official business in the importing country.

EXPORT OF UNREGISTERED PESTICIDES

Unregistered pesticides and pesticide devices must have bilingual labeling when exported to non-English speaking countries. The labels of these products also must include the statement "Not Registered for Use in the United States of America."

Anyone exporting unregistered pesticides must first obtain a signed statement from the foreign purchaser acknowledging that the purchaser understands that the pesticide is not registered for use in the United States and cannot be sold in the United States. This statement is called a Foreign Purchaser Acknowledgment Statement (FPAS) and must be obtained prior to the first export shipment of a particular unregistered pesticide to a particular purchaser for each country on an annual basis. The seller must send a copy of the FPAS to the EPA Office of Pesticide Programs (OPP), Field and External Affairs Division (FEAD); the inspector can find this form on file with OPP.

On January 18, 2013, EPA revised the regulations on labeling of pesticide products and devices intended solely for export. Unregistered pesticide products shipped between registered establishments operated by the same producer will have to follow the labeling requirements in 40 CFR Part 168. This rule is intended to ensure appropriate handling of unregistered pesticide products as they move in commerce before they actually leave the United States.

INSPECTION AND SAMPLING

Export inspections are generally conducted at producing establishments, but pesticides and devices intended for export may be encountered during port visits where pesticides might be stored pending export.

PROCEDURES

For routine inspections, the general procedure is to obtain evidence necessary to establish compliance with FIFRA and the export regulations. A checklist is provided to assist inspectors to ensure that all requisite activities have been covered (see Exhibit 12-1). For "for cause" inspections, follow the specific instructions on the EPA referral.

Most export inspections will be included along with FIFRA section 8 books and records inspections, conducted at producing establishments. These will involve the review and collection of export pesticide/device labels, shipping documents, sales invoices, statements, and other documents which can be used to document the export of pesticide/device products. Pesticides for export can be contract produced and shipped domestically to another company for exportation. In these cases, it may be necessary to conduct inspections at both the producing establishment and the company that is actually responsible for the exportation of the product. (See Chapter 9, "Establishment Inspections", for more information on producer establishment inspections).

The inspector should obtain a copy of the FPAS for each unregistered pesticide and cross-reference the date of the exporter's receipt of the FPAS with the actual date of sale or distribution of the unregistered pesticide. The unregistered pesticide **cannot be legally exported until the FPAS is received by the U.S. exporter**. Any sale or distribution of the unregistered pesticide prior to the exporter's receipt of the FPAS is unlawful, unless otherwise exempted by FIFRA section 17.

During export inspections, the inspector, through discussions with responsible company officials and subsequent review of company records, must be able to clearly document the items identified below. When information is not available or cannot be clearly documented by obtaining copies of records, the inspector must obtain a statement (use EPA Statement Form 3540-42; Exhibit 1-1) from responsible company officials that clearly documents the procedures used by the company when exporting pesticides or devices.

Some of the information to be obtained during these inspections may be claimed as FIFRA Confidential Business Information (CBI). See Chapter 1, "General Information", for more information on CBI.

PRE-INSPECTION ACTIVITIES (REGIONAL OFFICE FUNCTION)

The federal EPA inspector should conduct the following pre-inspection activities:

- Review and copy section 7 establishment production data submitted to the region and found in the Section Seven Tracking System (SSTS) or on copies of EPA Form 3540-16 submitted to the region for all registered/unregistered products or devices exported for the targeted calendar year(s).
- Develop a comprehensive list of registered/unregistered products or devices exported in the targeted calendar year(s) by the targeted establishment. Regional listings of registered/unregistered products or devices, product name and establishment name/address and other establishment and company information should be obtained from SSTS.
- Review and copy all Confidential Statements of Formula (CSFs) or chemical formulation statements, if available at the region, or obtained from the Office of Pesticide Programs for all products identified above. Develop a list of all unregistered products identified as not having product formulas on file prior to the inspection so that the inspector can obtain any missing formulas at the time of the inspection. Note on this listing if product formulas were not submitted to the region along with the production data in EPA Form 3540-16 for each calendar year. Product formulas may be CBI and shall not be shared with states that may conduct or be part of inspection activities.
- Assemble sampling equipment that will be taken on inspection. See a listing of suggested equipment in Chapter 7.

ON-SITE INSPECTION ACTIVITIES (REGIONAL/STATE FUNCTION)

The inspector must present credentials and issue a Notice of Inspection (NOI) (see Form 3540-2; Exhibit 1-1) to the owner/operator, or agent-in-charge. The reason for the inspection must be stated in the NOI and, if a violation is suspected, this must be disclosed in writing on the NOI.

For each registered/unregistered product or device exported in the targeted calendar year(s):

- Obtain evidence that clearly shows the company responsible for the product and its export. Obtain evidence that describes past and present corporate relationships, such as mergers, takeovers and/or other corporate transactions and any agreement expressing the nature and responsibilities between the companies involved in the export of the pesticide/device.
- Obtain copies of the CSF, if available; otherwise, obtain a copy of the complete formula of the product. (Note: The CSF and formula of the product contain confidential business information (CBI) and cannot be viewed, copied or obtained by a state inspector. An EPA federal inspector cannot view/copy the CSF unless cleared for CBI; state inspectors using federal credentials cannot obtain copies of the CSF's or any CBI materials. See Chapter 1 of this Manual.)
- Obtain copies of the specification or directions from the foreign purchaser for the production of such pesticides, devices or active ingredients. (40 C.F.R. 169.2(h)(1))
- Obtain copies of label(s) and supplemental labeling, including bilingual label(s), used for each export. (40 C.F.R. 169.2(h)(2)) If product label(s)/labeling are not available, obtain bin labels/labeling. In either case, the inspector shall obtain a statement (see Statement Form 3540-42; Exhibit 1-1) from the responsible company official certifying that the labels/labeling collected are identical to those used on the exported product. If a particular product label is being used for more than one country, the statement must include the name of each country.
- If registered/unregistered pesticides or devices are packaged, labeled and released for shipment at the time of the inspection, obtain a physical sample or obtain documentary evidence (labels/labeling and photographic evidence) of all such products.
- Obtain copies of all FPAS of a particular product to a particular purchaser for each importing country. (40 C.F.R. 169.2(h)(3))
- Obtain documentation showing the dates and amounts of each registered/unregistered product or device shipped and country of destination (e.g., bills of lading, manifests, invoices, consignee lists). (40 C.F.R. 169.2(d)) If these documents contain CBI, only federal EPA inspectors can obtain this documentation. See Chapter 1 for more information on CBI.
- Note in the inspection report if any of the documents above were not maintained by the facility. If the facility does not maintain records listed above, obtain a statement from

the responsible official as to why the records were not maintained by the facility and the actual location of the records/documents, if known.

- Request that copies of all missing records and/or product labels be sent to the EPA regional office by a specific date.

For instances where the facility/establishment claims that a product is for "research and development" or "experimental" purposes and a FPAS, therefore, was not required:

- Obtain a statement from the responsible company official specifically describing the basis for any such claims.

The FIFRA Export Inspection Checklist (Exhibit 12-1) will assist the inspector covering all the above items.

IMPORTS

Imported pesticides and devices are subject to the same registration, labeling requirements, and exemptions as domestically produced pesticides and devices. Prior to the import of pesticides or devices into the United States, the importer of record is required to submit a Notice of Arrival (NOA).

AUTOMATED COMMERCIAL ENVIRONMENT / INTERNATIONAL TRADE DATA SYSTEM (ACE/ITDS)

The International Trade Data System (ITDS) is the *single window* whereby regulated entities can electronically file and process their entry and agency-specific information for multiple agencies in a single location, rather than separately with each agency. The Automated Commercial Environment (ACE) implementation supports the ITDS; it is a platform that provides a single, centralized access point for the trade community to connect with CBP and its Partner Government Agencies (PGA).

As of December 31, 2016, EPA had commenced its required transition to the ACE system. The primary purpose of ACE is to automate electronic review of Notices of Arrival. While ACE electronically processes the majority of NOAs, importers may continue to file paper NOAs (EPA Form 3540-1), should they so choose. These paper NOAs will continue to be reviewed and approved by EPA as necessary.

ACE provides EPA with the ability to periodically check filings and allows for additional data mining to target inspections. Each region should develop a set of Standard Operating Procedures (SOPs) for using ACE within their region.

IMPORT OF UNREGISTERED PESTICIDES

Under certain conditions, unregistered pesticides will be allowed to enter the United States. These conditions are found in 40 C.F.R. 152.30 and in PR Notice 99-1. An unregistered pesticide may be imported if:

(1) It is transferred between registered establishments operated by the same producer (all EPA label requirements must be met, except the product should not have an EPA Registration Number or EPA Establishment Number). Where the establishments are not operated by the same producer, see 40 C.F.R. 152.30 for additional requirements;

(2) It is distributed for use under an experimental use permit (EUP);

(3) It is distributed for use under an emergency exemption;

(4) It is imported solely for the purpose of formulation or packaging; and for subsequent export provided certain requirements are met; see PR Notice 99-1, or

(5) It is imported for research and development purposes not requiring an experimental use permit (EUP).

IMPORT OF RESEARCH & DEVELOPMENT PESTICIDES

Substances, including mixtures of substances, being imported for research and development (R&D) must comply with FIFRA section 17(c) and 19 C.F.R. 12.110 through 12.117.

Substances are regulated either by FIFRA, the Toxic Substances Control Act (TSCA) or the Federal Food, Drug, and Cosmetics Act (FFDCA). If the substance is characterized as a pesticidal chemical, then it is regulated under FIFRA. If the substance is characterized as a pharmaceutical chemical, then it is regulated under FFDCA. Substances that are neither pesticidal nor pharmaceutical most likely are regulated under TSCA. TSCA exempts TSCA regulated R&D chemicals from the import requirements of the TSCA statute and regulations. FIFRA does not exempt pesticidal R&D chemicals from the import requirements.

An R&D product is deemed to be a pesticide when it has been determined by the company to have potential pesticidal potential properties. At that time, the company has determined that the product has pesticidal value and further research will be conducted to support registration. The inspector may encounter an R&D product at universities, laboratories or sponsors performing research, or possibly ports of entry for imports.

IMPORT OF REGISTERED PESTICIDES AND DEVICES

Before registered pesticides or devices can be imported into the United States, the importer must submit a Notice of Arrival. The EPA regional office shall:

- Complete Part II of the NOA, indicating the disposition to be made of the shipment of pesticides or devices upon its arrival in the United States.

- Return the completed NOA to the importer or its agent.

Normally, an import broker will represent the importer in obtaining CBP clearance.

Upon the arrival of a shipment of pesticides or devices, the importer (or broker) shall present to Customs and Border Protection (CBP) at the port of entry the NOA completed by the EPA regional office indicating the appropriate CBP action to be taken with respect to the shipment.

FOREIGN-TRADE ZONES

Foreign-trade zones (FTZ)(known internationally as free-trade zones) are secure areas legally outside the customs territory of the United States. They are usually located in or near CBP ports of entry, industrial parks or terminal warehouse facilities. CPB is responsible for activating foreign-trade zones, securing them, controlling dutiable merchandise moving in and out of them, protecting and collecting the revenue. Merchandise lawfully brought into these zones may be stored, sold, exhibited, broken up, repacked, assembled, distributed, salvaged, relabeled, destroyed, processed, graded, cleaned, mixed with foreign or domestic merchandise, or otherwise manipulated or manufactured. Imported pesticides, registered or not, require notification to EPA upon arrival into these zones.

Pesticides entering foreign-trade zones typically involve one of three scenarios:

- Import comes in to FTZ and is destined immediately for entry into United States commerce.
- Import comes in to FTZ and further production occurs (e.g. formulation, labeling, or packaging changes); pesticide product leaving the FTZ is either distributed into United States commerce or is exported.
- Import comes in to FTZ and is exported at some later date.

REGIONAL OFFICE

The EPA regional office supervisor/import coordinator and pesticide inspectors should maintain a cooperative working relationship with CBP and customs brokers. This is vital to understanding the way each different port of entry conducts its business. Upon receipt of the NOA, the regional office should review the NOA for completeness and determine whether to inspect and/or sample based on the following:

- Pesticides/devices suspected of noncompliance (e.g., unregistered pesticides and/or unregistered establishments).
- Pesticides/devices with a violative history (the region may have knowledge of a violative product or company).
- First-time import of a pesticide/device to the region.
- Pesticides/devices imported regularly with a good history of compliance (i.e., high volumes).

If a decision is made to inspect the imported pesticide/device, indicate in Part II of the NOA what action to take or take appropriate action via ACE. The options are:

- Detention of the pesticides/devices by CBP for inspection by EPA. The expenses associated with the detention must be borne by the importer. It is important that the inspection be conducted as soon as possible since the fate of the shipment is determined by the inspection. This type of inspection is likely to occur at the port of entry, as the shipment is not usually released to the importer until EPA determines compliance. The shipment may have been picked up by the consignee under an immediate delivery entry (usually an electronic entry) (19 C.F.R. 142.21-142.22). In such cases, the shipping company or the import broker should be requested to locate and hold the product for inspection.
- Release of the shipment of pesticides/devices under bond. See 19 C.F.R. 113.61 and 113.62. In accordance with section 17(c) of FIFRA, EPA may instruct CBP to release a shipment of pesticides/devices under a bond for the return of the imports to the custody of CBP. When this option is chosen the shipment is technically being detained because the pesticides/devices cannot be used or otherwise disposed of until EPA conducts an inspection and makes a determination. This type of inspection will take place at the consignee's facility and must proceed following normal protocol for establishment inspections. Whenever circumstances permit, EPA should consult with CBP personnel at the port of entry to ensure that the bond set by CBP is of an amount significant enough to compel the importer to hold the shipment for inspection. Circumstances such as prior knowledge of the quantity and/or estimated value of the shipment as well as the status of the cooperative working relationship between EPA and CBP personnel at the port of entry will dictate the feasibility of such a consultation. In special circumstances where concern exists that a bond may not stop distribution of the products, the EPA regional office should consider issuing a Stop Sale, Use or Removal Order (SSURO).

If the EPA regional office instructs CBP either to detain the imported pesticides/devices, or to release the shipment under a bond, an EPA inspector must be prepared to conduct an inspection. Documentary samples of labels and/or pesticides/devices can be taken to determine compliance with FIFRA.

If released under bond, the commodity may likely be moved to a "bonded warehouse", or other location under bond away from the port of entry. The container(s) are still under CBP control, but the Notice of Inspection and Receipt for Samples will be issued to the bonded warehouse owner, or responsible party (not to CBP). NOTE: At a bonded warehouse only the stevedores can open and unload a container of imported or exported goods at ports of entry or bonded warehouses. The location of detained pesticide import shipments is determined by CBP and carried out by the import broker. The location will be a CBP licensed and bonded warehouse operated by a private storage/warehouse company, or to a location taken under bond and determined by CBP.

INSPECTIONS AND SAMPLING

Imported pesticides/devices can be inspected at different ports of entry or other locations depending on how the shipment arrived in the United States and the CBP status of the shipment.

Upon arrival at the inspection site, the inspector must introduce himself/herself to CBP, the warehouse owner and other parties and must present federal credentials (as all import inspections are conducted under FIFRA sections 8 and 9), explain the purpose of the inspection and issue a Notice of Inspection (Form 3540-2, see Exhibit 1-1) with the reason for inspection. The Notice of Inspection must be issued to the person who has control of the product at the time of the inspection. CBP never takes custody of the product during the importation/entry of the shipment. Thus, the Notice of Inspection is never issued to CBP; rather, it will be issued to the importer, import broker, bonded warehouse owner or shipper of the import.

An inspector's checklist for imports is provided at Exhibit 12-2.

IMPORT SAMPLING

Physical samples should be collected if EPA suspects that the pesticide product has been adulterated or suspects that the composition of the pesticide product is different from the CSF in connection with the registration of the product. For all other suspected or observed violations, documentary samples are sufficient to demonstrate a violation of FIFRA and provide sufficient weight of evidence to instruct CBP to refuse entry of the import shipment, if necessary. Documentary samples will always include photographs of the label and labeling on the pesticide, cases or containers in the import shipment.

The inspector must take the following steps when obtaining samples:

- Issue a Receipt for Samples for any samples taken. Use EPA Form 3540-3, see Exhibit 1-1. Give the Receipt to the individual that received the Notice of Inspection.
- If physical samples are obtained, submit the sample to the appropriate laboratory and ask the laboratory to expedite the analysis, following chain-of-custody procedures.
- Inform the EPA supervisor/import coordinator that a sample has been collected and sent for analysis, specifying the name of the laboratory.
- When taking a sample, it is recommended that the inspector also obtain a statement to document information about the sample. Use EPA Form No. 3540-42, Exhibit 1-1.

Following a sample collection, and while waiting for chemical analysis or case review, the pesticide will have to be detained. The import broker and CBP agent must determine the location where the pesticide is held. The shipment must be kept intact until EPA makes a determination of compliance. The inspector should exchange telephone numbers with all parties involved, so as to expedite communication regarding further actions with regard to the commodity.

INSPECTION WITHOUT SAMPLING

Prior to inspection of detained shipments, a copy of the label should be obtained from the EPA product manager in the Office of Pesticide Programs or from the Pesticide Product Labeling System (PPLS) at: https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1.

When conducting an inspection without sampling, the inspector should complete the following steps:

- Present credentials.
- Issue the Notice of Inspection.
- Review the labeling for mandatory label requirements.
- Check for collateral labeling such as booklets and pamphlets.
- Check condition of the lot or batch of product.
- Review and copy all import records, bills of lading, manifests and other documentation.

If a label or labeling violation is noted, the inspector should photograph or photocopy the label for documentary evidence. See Chapter 6 for more information on sampling procedures.

EPA REGIONAL OFFICE PROCEDURE AFTER INSPECTION

MERCHANDISE IN COMPLIANCE WITH FIFRA

If the imported pesticide/device is found to be in compliance with FIFRA, the regional office must notify CBP that the shipment may be released to the consignee. A model Release Notice is included as Exhibit 12-3.

One way to standardize the way EPA regions notify CBP that the shipment may be released may be to "cc" the District Director of CBP at the port of entry on a Release Notice addressed to the importer of record. For purposes of expediting the Notice, EPA regional personnel should fax a copy of the release notice to their CBP staff counterpart at the port of entry.

MERCHANDISE IN VIOLATION OF FIFRA

If the imported pesticide/device is found to be in violation of FIFRA, the EPA regional office must refuse admission of the pesticides/devices into the country. EPA must notify the consignee of this refusal. This procedure is consistent with the CBP regulation in 19 C.F.R. 12.117(b). A model Notice of Refusal of Admission is found at Exhibit 12-4. See Exhibit 12-5 for a Notice of Detention and Hearing. The consignee is given 20 days to submit written material or, at the option of the consignee, appear before EPA and introduce testimony to show cause why the shipment must not be destroyed or refused entry. If no hearing is requested or, after consideration of the evidence, it is still the opinion of EPA that the shipment is in violation of FIFRA, the importer has 90 days from the date of receipt of the Notice of Refusal of Admission to export the violative products out of the U.S.

One way to standardize the way regions notify CBP that the shipment has been refused admission may be to "cc" the District Director of CBP at the port of entry on a Notice of Refusal of Admission addressed to the importer of record. For purposes of expediting the Notice, EPA Regional personnel should fax a copy of the Notice to their CBP staff counterpart at the port of entry. If this does not occur, CBP, in cooperation with EPA, may oversee the destruction of the pesticides/devices, although this is done as a last resort because of the expense to CBP and the public.

Possible violations of FIFRA can include any of the unlawful acts described in sections 12(a)(1) and 12(a)(2) of FIFRA. These include but are not limited to: distribution of an unregistered pesticide, distribution of a misbranded or an adulterated pesticide or device, and failure to file reports required by FIFRA. Stop Sale, Use, Removal Orders (SSUROs) and Seizures under section 13 of FIFRA can be issued for imports suspected of being in violation of the Act. **NOTE:** There is always an importer of record for every import shipment and it is this person who is held liable for any violations. Import brokers act as agents of the importer of record and become jointly liable if a violative product is found to be distributed (imported) into the United States. A FIFRA import inspection checklist (Exhibit 12-2) will assist the inspector.

Pesticides and devices may also be inspected by CBP and sampled following release of the product to a point of destination (not released under bond). The FIFRA Notice of Arrival of Pesticides and Devices (EPA Form 3540-1, Exhibit 1-1) will list the destination of the shipment. Therefore, the inspector can also conduct an import inspection at the destination location. Should there be any discrepancies, the inspector should notify the EPA supervisor immediately to determine the next steps by EPA and/or CBP.

EXHIBIT 12-1: FIFRA EXPORT INSPECTION CHECKLIST

Company: _____ Establishment No.: _____

Address: _____

Inspection Date: _____

Inspector's Name and Phone Number: _____

Product(s) Name and (EPA Reg. #): _____

EPA Establishment Number: _____

Part I - Documentation Obtained **Yes/No/Exhibit #**

1. Are §7 production reports (EPA Form 3540-16) included for this product for each targeted calendar year? [If reporting discrepancies were found, note in "Comments" section on page 2 of this form.]
2. Is the Confidential Statement of Formula or chemical formula included for this product?
3. Are production specifications/directions of the foreign purchaser included for this product?
   If not, take a statement from the appropriate company official as to why these records are not maintained by the facility. Is the actual location of the records known and included?
4. Are label(s)/supplemental labeling included for this product for each country to which it was exported?
   No. of countries: _____ No. of labels: _____
5. If product labels/labeling were not available, are bin labels included for this product?
   Take a statement from the responsible company official which should state whether or not the labels/labeling or bin labels/labeling collected are identical to those used on the exported product(s)?
   Is photographic evidence of the product that was packaged, labeled and released for shipment at the time of the inspection included?
6. If labels were not available for inspection, is a statement from the appropriate company official included as to why labels were not maintained by the facility? Is the actual location of the labels known and included?
7. Are Foreign Purchaser Acknowledgment Statements (FPAS), as required by §17(a)(2), included for the first shipment each year of a

particular product to a particular purchaser for each importing country?
If not, is a statement included?

8. If the unregistered product was claimed to be a "research & development" or an "experimental" pesticide, is a statement included from the responsible company official specifically describing the basis for such claims?
9. **OPTIONAL**: If the unregistered product is claimed "substantially similar" to an EPA registered product, is a copy of the label for the registered product and Confidential Statement of Formula or chemical information for the registered product included?
10. Is evidence of exported shipments included that **clearly** shows the product name, date(s) of each shipment, amounts of each shipment, and country of destination for each shipment? (This can include Bills of Lading, Invoices and List of Consignees.)
11. Is evidence included that clearly shows the company responsible for the product and its export? Is evidence included that clearly describes past and present corporate relationships, such as, mergers, takeovers and/or other corporate transactions/agreements?
12. Was information included for this product for all periods requested?

COMMENTS: _____

_____

_____

Part II - Labeling Requirements and Review

Does the label/labeling for this exported product bear the following information? Attach a separate Part II sheet for each product label and foreign destination.

Product Name: _____ Foreign Destination: _____

		Yes	No
1.	EPA Establishment Number?		
2.	Ingredient statement?		
3.	Name/address of producer/registrant?		
4.	Statement of net weight or measure?		
5.	Use Classification statement? (Restricted Use or General Use Pesticide)		

6. Precautionary statements? (Warning and caution statements)
7. If highly toxic, are “skull & crossbones,” the word Poison and statement of practical treatment shown?
8. For unregistered products, does label bear the statement “Not Registered for Use in the United States of America”?
9. If the predominant language of the importing country is not English, are #’s 2, 6, 7 and 8 above also expressed in the language of the importing country? (Note that this information is required on both **registered and unregistered** products.)

Label Comments: _____

_____

_____

_____

EXHIBIT 12-2: FIFRA IMPORT INSPECTION CHECKLIST

For use after the regional office import coordinator determined that a shipment is to be inspected and setup a location for the inspection.

1. Inspector's name/number: _____
2. Location of shipment to be inspected: _____

_____

_____

Obtain the following information from the Notice of Arrival (NOA) Form 3540-1 or the papers accompanying the shipment.

3. Importer/Consignee Address	4. Shipper Address
5. Broker Agent Address	6. Carrier

7. EPA Registration Number _____ 8. EPA Establishment Number _____

9. Brand Name of Product _____

10. Major Active Ingredients and Percentage of Each _____

_____

_____

_____

_____

_____

11. Unit Size _____ 12. Quantity _____ 13. Total Net Weight _____

Inspection Procedures	**Check if applicable**
14. Obtain a copy of the EPA approved label from the EPA regional office.	
15. Issue NOI and show federal credentials to appropriate person.	
16. Collect photographs of the label(s) and labeling on the container(s) of the import shipment. Review for conformity with label requirements. (Procedures for conducting label reviews can be found in the FIFRA Inspection Manual.)	
17. Collect all records regarding import of shipment such as: Copies of NOA Foreign invoices Shipping records (i.e., manifests or waybills)	_____ _____ _____
18. Review other label information in books, pamphlets, circulars and displays—if applicable.	
19. Document the physical condition of the lot.	
20. Photograph containers and the labels thereon.	
If physical samples are taken, follow these additional steps	
21. Note on the Receipt for Sample that it is an import sample and identify with "IMP" preceding the sample number.	
22. Request that the laboratory expedite the analysis.	
23. Ensure that the product container is properly resealed.	
24. Notify the regional office that the samples have been collected.	

EXHIBIT 12-3: MODEL RELEASE NOTICE

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Name
Title
Company Name
Company Address

Re: RELEASE NOTICE
Entry Number (Assigned by Customs and Border Protection) (Product Name)

Dear (Company President's Name):

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act), 7 U.S.C. 136 *et seq*., the United States Environmental Protection Agency has completed its consideration of the following shipment. Base on examination of samples or other evidence, the Agency concludes that, pursuant to section 17(c) of the Act, you need not further detain the merchandise.

Sample Number (if an inspection has been conducted):

Product Name:

Shipper/Manufacturer:

Consignee:

Entry Number:

Date of Importation:

Port of Entry:

This Notice does not constitute assurance that the merchandise involved complies with all provisions of the Act and in no way precludes further action should the Agency determine that the merchandise is in violation of any federal environmental requirement.

Sincerely,

/s/

(Name and Title)

EXHIBIT 12-4: MODEL NOTICE OF REFUSAL OF ADMISSION

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Name
Title
Company Name
Company Address

Re: NOTICE OF REFUSAL OF ADMISSION
Entry Number (Assigned by Customs and Border Protection) (Product Name)

Dear (Company President's Name):

In connection with the enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act), 7 U.S.C. 136 *et seq*., the United States Environmental Protection Agency has examined samples or other evidence with respect to the following shipment:

Sample Number (if an inspection has been conducted):
Product Name:
Shipper/Manufacturer:
Consignee:
Entry Number:
Date of Importation:
Port of Entry:

It appears that the product is not in compliance with the Act and is subject to refusal of admission due to the following violations (Describe violations).

The Agency hereby notifies you that your merchandise has been refused admission. You must export this merchandise, under supervision of the U.S. Customs and Border Protection (CBP), within ninety (90) calendar days from the date of this Notice (or within such time as otherwise specified by EPA) or within such additional time as the District Director of CBP specifies. Failure

to do so may result in either the destruction of the merchandise as authorized by the Act, or, if the shipment has been released to you under bond, in any action necessary to enforce the terms of said bond.

Sincerely,

/s/

(Name and Title)

EXHIBIT 12-5: MODEL NOTICE OF DETENTION AND HEARING

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Name
Title
Company Name
Company Address

Re: NOTICE OF DETENTION AND HEARING
Entry Number (Assigned by Customs and Border Protection) (Product Name)

Dear (Company President's Name):

In connection with the enforcement of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA or the Act), 7 U.S.C. 136 *et seq*., the United States Environmental Protection Agency has examined samples or other evidence concerning the shipment described below and has determined that said shipment is in violation of the Act. You should continue to withhold the merchandise from distribution or sale pending a final decision as to whether it shall be admitted or refused admission.

Pursuant to Section 17(c) of the Act, the Agency hereby affords you an opportunity to offer such explanation as you wish for the Agency's consideration. You should file your answer, signed by you or your attorney, with this office within twenty (20) calendar days after your receipt of this Notice. Please indicate in your response if you wish to present your views verbally so that we may set a date for such presentation to be held in this office or via teleconference.

Sample Number (if an inspection has been conducted):
Product Name:
Shipper/Manufacturer:
Consignee:
Entry Number:
Date of Importation:
Port of Entry:

Upon examination, it appears the product(s) failed to comply with the provisions of the Act in that (describe violation). I am enclosing a copy of EPA's FIFRA Enforcement Response Policy.

Sincerely,
/s/ (Name and Title)

CHAPTER THIRTEEN
CANCELLATION AND SUSPENSION

CONTENTS

Statutory Authority 2
Cancellation 2
Suspension 3
Inspection Objective 3
Procedures During Inspections 4
Producer Establishment Inspections 4
Marketplace Inspections 4
Use Inspections 5
Storage and Disposal of Suspended or Canceled Pesticides 5

CANCELLATION AND SUSPENSION

STATUTORY AUTHORITY

FIFRA sections 3(c)(2)(B), 4(d) and 4(f) provide the Administrator with the authority to cancel and/or suspend the registration of a pesticide for failure of the registrant to provide, or commit to provide, data required by the Agency.

FIFRA section 6 provides the Administrator with the authority to cancel the registration of a pesticide for unreasonable adverse effects on the environment or to suspend the registration if it is necessary to prevent an imminent hazard.

FIFRA section 13 provides the Administrator with the authority to issue Stop Sale, Use, Removal Orders (SSURO) and Seizure whenever there is reason to believe on the basis of inspection or tests that a pesticide or device has been or is intended to be distributed or sold in violation of FIFRA or when the pesticide has been cancelled or suspended.

The Administrator cancels the registration of a pesticide at the end of five years unless the registrant (or other interested party acting with the registrant's concurrence) requests renewal of the registration before the end of the five years.

FIFRA section 12(a)(2)(J) makes it unlawful to violate any suspension order issued under sections 3(c)(2)(B), 4 or 6.

FIFRA section 12(a)(2)(K) makes it unlawful to violate any cancellation order issued under the Act or to fail to submit a notice in accordance with section 6(g).

FIFRA section 12(a)(1)(A) makes it unlawful to distribute or sell any pesticide that is not registered under section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under FIFRA.

CANCELLATION

EPA is authorized to cancel a pesticide registration when existing risks related to the use of the pesticide are unacceptable and registrants either have not made, or cannot make, necessary changes to the terms and conditions of the registration to address the unacceptable risks. In addition, EPA can cancel a pesticide registration for reasons unrelated to risk, such as nonpayment of maintenance fees. Registrants can voluntarily cancel pesticide registrations at any time. When the Agency decides to cancel the registration of a pesticide product, it prepares a Notice of Intent to Cancel (NOIC) that is published in the Federal Register and sent to registrants. The Agency then provides a Final Cancellation Order, which is also published in the

Federal Register and sent to registrants. The Cancellation Order includes the date by which the product may no longer be produced, sold and distributed.

SUSPENSION

EPA may suspend pesticide registration pursuant to FIFRA section 3(c)(2)(B) to halt further distribution and sale of a pesticide product by the registrant and any supplemental registrants or supplemental distributors until the suspension is lifted by EPA. Consumers who have already purchased such products may continue to use them according to the labels. Product suspension is most common when EPA determines that additional data is required to support an existing registration of a pesticide. In such cases, the Agency notifies all registrants of the pesticide through issuance of a FIFRA Data Call-In Notice (DCI). The DCI will require each affected registrant to provide evidence within 90 days that the affected registrant is taking appropriate steps to respond to the DCI. It also sets deadlines for the data submission and may specify interim deadlines. If a registrant fails to comply with a DCI requirement, EPA may issue a Notice of Intent to Suspend (NOIS) the registration of the pesticide. If the registrant fails to submit timely or adequate data to satisfy the DCI or fails to take any additional step required by the DCI, EPA may suspend the pesticide. The suspension becomes final and effective 30 days after EPA issues the NOIS, unless within that time period, one of the following two things happens:

- The registrant demonstrates that it has fully complied with the requirements that served as a basis for the NOIS, or
- A person adversely affected by the Notice makes a timely and adequate request for a hearing. If a hearing is requested, it will be conducted according to the requirements of FIFRA section 6(d) and the procedural regulation at 40 C.F.R. Part 164.

Under special circumstances, a registrant may be allowed continued sale or use of existing stocks of canceled and/or suspended pesticide products.

INSPECTION OBJECTIVE

The inspector's role is to gather the information necessary for EPA to determine compliance with the Agency's suspension or cancellation order. It is the policy of EPA to follow up all suspension and/or cancellation orders with appropriate surveillance and regulatory action, as dictated by the nature of the suspension or cancellation order. Compliance monitoring strategies are generally developed for each suspension and/or cancellation order.

The inspector should be aware that not all suspended pesticides present a risk or imminent hazard. If there is any question about the basis for the suspension, treat the product as posing a potential hazard. Inspectors may find an updated list of all currently suspended pesticides at https://www.epa.gov/pesticide-reevaluation/suspension-registrations-under-fifra.

PROCEDURES DURING INSPECTIONS

The regional office can provide the inspector with a copy of the suspension order, which will include the basis for the suspension. The inspector must carefully review and be familiar with the terms of the suspension or cancellation order, since terms may vary. For example, producers cannot continue to produce cancelled products and may only sell "existing stocks" of products (i.e., products already produced and packaged for sale as of the date of the cancellation order).

PRODUCER ESTABLISHMENT INSPECTIONS

If canceled or suspended pesticides are discovered during a producer establishment inspection, the inspector should take the following steps:

- Immediately notify his/her EPA supervisor about the production of a canceled or suspended product. The EPA supervisor will decide whether a SSURO or other action is appropriate.
- Gather production records associated with the cancelled or suspended product, showing the date, quantity, batch number (if available) of production.
- Gather the dates and distribution records associated with the cancelled or suspended product, showing the date, quantity and recipient of each shipment.
- Obtain an official sample of the product.
- Determine whether the products are being held for disposal. If held for disposal, inventory the lot and determine what disposal steps have been taken.
- Determine if and when the establishment was notified of EPA's order.

MARKETPLACE INSPECTIONS

If canceled or suspended pesticides are discovered during marketplace inspections, the inspector should take the following actions:

- Immediately notify his/her EPA supervisor about the production of a cancelled or suspended product. The EPA supervisor will determine if a SSURO or other action is appropriate.
- Document the receipt of the shipment by the marketplace establishment.
- Document the further sale or distribution by the marketplace establishment.
- If the product was shipped in violation of a cancellation/suspension order, visit the producer to determine whether other consignees may be involved. This may require

that the inspector/EPA supervisor coordinate this activity if the producing establishment is in another state or EPA region.

- In documenting shipment, distribution, sale, etc. of canceled or suspended products, document individual batch numbers of the products as well as sales records for products.
- Link the product from the marketplace back to the producing establishment (by way of a dealer) to the registrant of the product.

USE INSPECTIONS

If canceled or suspended pesticides are discovered during use inspections, the inspector should contact his/her supervisor to initiate the process for issuing a SSURO.

STORAGE AND DISPOSAL OF SUSPENDED OR CANCELED PESTICIDES

FIFRA Section 19 provides EPA with the authority to regulate the storage, transportation and disposal and recall of pesticides. In addition to the authority to require data on storage and disposal methods, FIFRA also authorizes EPA to establish labeling requirements for transportation, storage and disposal of the pesticide and its container. The law also enables EPA to take enforcement action for violations (see FIFRA sections 19(a) and 6(g)). EPA may require registrants and distributors to recall suspended and canceled pesticide products. The Agency is authorized, pursuant to FIFRA section 19(a)(1)(c) to require registrants to give evidence of their financial capacity to carry out such a recall.

To facilitate any recalls of this kind, EPA may require all persons who sell, distribute or commercially use pesticides to notify EPA, state, local and tribal officials of the quantities and locations of suspended and canceled pesticides in their possession.

A registrant who wishes to become eligible for reimbursement of storage costs incurred as a result of a recall must submit a plan of storage and disposal of the pesticide that meets criteria set forth in FIFRA Section 19. Registrants will be reimbursed for portions of their storage costs that are attributable to delays in approval of storage plans.

A producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide who possesses a pesticide that has had its registration canceled or suspended must notify the Administrator and appropriate officials in accordance with the Order. The notification must include the following information:

- The quantity of the pesticide in possession.
- The place at which the pesticide is stored.

CHAPTER FOURTEEN
STOP SALE, USE, OR REMOVAL ORDERS

CONTENTS

Statutory Authority....2
Background....2
Procedures....3
Serving the SSURO....3
Refusal to Accept SSURO....4
No One Available to Accept Service of the SSURO....4
Disposing of Pesticides Covered by a SSURO....4
Follow-up Inspections....4
Violations of a SSURO....5
Exhibit 14-1: Model Stop Sale, Use, or Removal Order....6

STOP SALE, USE, OR REMOVAL ORDERS

STATUTORY AUTHORITY

FIFRA section 13(a) authorizes the Administrator to issue a Stop Sale, Use, or Removal Order (SSURO) to any person who owns, controls or has in their custody any pesticide or device where:

- The Administrator has reason to believe that the pesticide or device is in violation of any provision of the Act;
- The violative pesticide or device has been or is intended to be distributed or sold in violation of FIFRA; or
- The pesticide has been suspended or cancelled.

After EPA issues a SSURO against a pesticide or device, no person can sell, use, or remove the pesticide or device except in accordance with the provisions of the SSURO.

FIFRA section 13(b) authorizes the seizure of any pesticide or device for confiscation and condemnation. Section 13(c) sets forth requirements for the disposition of pesticides or devices after condemnation.

FIFRA section 12(a)(2)(I) makes it unlawful for any person to violate any order issued under section 13.

BACKGROUND

SSUROs may be issued any time a pesticide or device is in violation of the Act. SSUROs, however, are generally reserved for situations involving a potential hazard to health or the environment. A SSURO:

- Can be expeditiously issued when EPA has a reason to believe a product is in violation of FIFRA.
- Extends to all of the violative pesticide material or devices under the custody or control of the person to whom the order is served.
- Keeps the responsibility for product disposal with the person to whom the order is served.

A SSURO will be prepared by EPA headquarters or a regional office. See Exhibit 14-1 for an example of a SSURO. The following summarizes the steps in the SSURO process:

- Identify the violation and develop evidence to support the existence of the violation.

- Prepare a complete description of the pesticide or device for EPA to include in a SSURO, such as the address of the product location, the EPA Registration Number, EPA Establishment Number, active ingredients, or product batch or lot codes.
- Prepare and issue the SSURO.
- Monitor compliance with the SSURO.
- Amend the SSURO as necessary to allow movement of the product for final disposition.
- Vacate the SSURO upon compliance with FIFRA or disposal or reconditioning of the material.

PROCEDURES

SERVING THE SSURO

Only EPA may issue federal SSUROs. However, EPA may request that a state inspector serve SSUROs at specified locations. The SSURO is served to the owner, operator or agent in charge of the establishment which has custody of the violative pesticide product or device. SSUROs are also served upon the registrant at its headquarters location if the establishment with custody/control isn't the same as the owner. EPA headquarters or the regional office may elect to serve the SSURO in person or by certified mail (return receipt requested).

The inspector should begin the service of the SSURO like an inspection, with presentation of credentials and Notice of Inspection. The "Violation Suspected" section of the Notice of Inspection must match the violation described in the SSURO. The inspector must explain to the recipient the scope and meaning of the SSURO and the obligation which it places on him/her as recipient. The explanation must include the fact that the product covered by SSURO cannot be sold, used or removed unless the SSURO is amended or vacated by a further SSURO issued by the EPA regional office or headquarters. The inspector must also provide the name of the EPA contact person.

The inspector can then review and collect records, as necessary, to document violative activity, and take inventories, if not done previously. If any samples or documents are collected, the proper inspection and sample collection procedures must continue to be followed.

The inspector will determine the amount of the product covered by the SSURO that is under the control of the person to whom the order is served. This information can be listed on a Notice of SSURO (EPA Form 3540-27; see Exhibit 1-1), affixed to the product(s) and also reported to the EPA regional office and/or headquarters. This Notice of SSURO is not to be used in lieu of a SSURO, but may be used to identify product inventory which is subject to a SSURO already issued.

REFUSAL TO ACCEPT SSURO

In the event that the person to whom the order is served refuses to accept the SSURO, the inspector shall leave a copy of the order at the establishment and explain the following to the recipient:

- The SSURO becomes effective when delivered and is binding on the recipient whether or not he/she accepts it.
- The recipient may discuss the SSURO with the contact person at EPA who is named in the SSURO.
- The recipient may be liable for a civil and/or criminal penalty for violating the terms of the SSURO as well as for the violation described in the SSURO.

The inspector should make a detailed record in his/her field notebook of this conversation and his/her actions for possible use at any subsequent hearing or court action.

NO ONE AVAILABLE TO ACCEPT SERVICE OF THE SSURO

If an inspector attempts to deliver a SSURO and the owner or agent is not present, a copy of the SSURO may be attached to the entry door of the establishment but another copy must be served by certified mail (return receipt requested) or similar method and tracked. The inspector should keep a record of his/her actions.

DISPOSING OF PESTICIDES COVERED BY A SSURO

EPA may issue a subsequent SSURO to permit the custodian of the product to bring the product into compliance or to properly dispose of it. Such orders can either be served in person, by certified mail or a method where delivery can be tracked. The original SSURO must be amended or terminated to permit movement of the product.

FOLLOW-UP INSPECTIONS

Inspectors should consult with EPA prior to follow-up inspections to assure compliance with a SSURO. Standard inspection procedures should be followed. Presentation of credentials and a written Notice of Inspection must be issued stating that the purpose of the inspection is to assure compliance with the SSURO issued on the pesticide(s) or device(s) listed in the SSURO. The inspector must confirm that the owner or agent received the SSURO and record the date received, if possible. The stock affected by the SSURO must be counted and documented, including package sizes and lot numbers. Any discrepancies between quantities in inventory and amounts stated in the SSURO must be resolved and documented.

In addition to the above information, the inspector should:

- Confirm that the company satisfied the data requirements that were the basis of the suspension or voluntarily cancellation, if applicable, by obtaining a copy of an official notification by the Office of Pesticide Programs that the requirements were satisfied and the SSURO was lifted. After obtaining this documentation the inspector may terminate the inspection.
- Determine if the company has requested or received any additional guidance from EPA concerning disposal. If so, copy and identify the guidance document(s). Provide the name of the state organization that will assist the company with disposal.
- Determine if the company has informed producing distributors and/or contacted manufacturers. If so, copy and identify record(s) of these contacts.
- Inspect production records for products named in the order and compare them to the effective date of the SSURO.
- Photograph or photocopy records showing production after the effective date of the SSURO or last production prior to the effective date. Depending on the specifics of the SSURO, production may not be prohibited but sale and distribution of the violative product are prohibited. To determine whether there have been unlawful sales, it is necessary to look at production records. The volume of production after the notification must physically remain in stock at the producing establishment. Shipping records can also be reviewed to establish whether or not products have been sold or distributed. If the SSURO is batch/lot specific, the SSURO may not prohibit production or sale/distribution of product not included in the violative batch/lot.

Some information obtained during the follow-up inspections may be claimed as FIFRA CBI (Confidential Business Information). For more information on CBI, see Chapter 1.

VIOLATIONS OF A SSURO

If a violation of a SSURO is discovered during a follow-up inspection, the inspector must:

- Report the violation to the EPA regional or headquarters office immediately.
- Document the violation (including the name, title and duties of the person responsible for the violation) and send a written report to the EPA regional or headquarters office.

EXHIBIT 14-1: MODEL STOP SALE, USE, OR REMOVAL ORDER

(Note – Currently, EPA's OECA is developing an improved model SSURO that will be inserted as Exhibit 14-1 when it becomes available.)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION __
STREET ADDRESS
CITY, STATE ZIP CODE

IN THE MATTER OF	)	**Stop Sale, Use or Removal Order**
Respondent's Name	)	
Respondent's Address	)	*DOCKET NO: FIFRA-* (docket number)
Respondent's City, State and Zip Code	)	
	)	
	)	
_____	)	

I. AUTHORITY

1. This Stop Sale, Use, or Removal Order ("Order") is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency ("EPA") by Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (AFIFRA"), 7 U.S.C. §136k(a), which authorizes the Administrator of the EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that, (Name of the pesticide, device or product), the pesticide or device is in violation of any provision of FIFRA, or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA. This authority was redelegated to the Regional Administrator of EPA Region __ on (date) by Delegation No. 5-12, and was further redelegated within EPA Region __ to the Director of (division name) Division and to the Associate Director for (office name) on (date).

2. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. §136*j*(a)(1)(A), makes it unlawful for any person in any State to sell or distribute to any person any pesticide that is not registered under Section 3 of FIFRA, 7 U.S.C. §136*a*, or whose registration has been canceled or suspended unless otherwise authorized by EPA under FIFRA.

3. Pursuant to Section 3(a) of FIFRA, 7 U.S.C. §136*a*(a), no person in any State may distribute or sell to any person any pesticide that is not registered under FIFRA.

4. Pursuant to Section 2(u) of FIFRA, 7 U.S.C. §136(u), the term "pesticide" includes "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."

5. Pursuant to Section 2(t) of FIFRA, 7 U.S.C. §136(t), the term "pest" includes fungus, bacteria and "other microorganisms."

6. The regulations implementing FIFRA give further guidance on what constitutes a pesticidal purpose, stating that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if, among other things, the person who distributes or sells the substance "claims, states or implies (by labeling or otherwise) . . . [t]hat the substance . . . can or should be used as a pesticide." 40 C.F.R. §152.15(a)(1). In addition, a substance is considered to be a pesticide requiring registration if the person who distributes or sells the substance "has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose." 40 C.F.R. §152.15(c).

7. Pursuant to Section 2(gg) of FIFRA, 7 U.S.C §136(gg), to Adistribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.

8. Sections 2(gg) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§136(gg) and 136j(a)(1)(A), make it unlawful for any person to "offer for sale" any pesticide if it is unregistered. EPA's regulations at 40 C.F.R. §168.22 clarify that such prohibition extends to advertisements in any advertising medium to which pesticide users or the general public have access.

9. This Order requires *(Respondent's Name)* to stop the sale, use, or removal of unregistered pesticides owned, controlled, or in its custody at or from its establishment located at or in the vicinity of (Respondent's Address), or at or from any other establishment wherever located. *(Respondent's Name)* shall undertake all actions required by this Order, and comply with all requirements of this Order, including any subsequent modifications to this Order.

II. BASIS FOR ORDER

10. *(Respondent's Name)* ("*Respondent Name*") or "Respondent"), located at *(Respondent's Address)*, is a Aperson" as that term is defined at Section 2(s) of FIFRA, 7 U.S.C. §136(s).

11. Respondent is and, at all times relevant to this Order, was the owner and/or operator of an establishment located at or in the vicinity of located at ___(*Respondent's Address*)___ (the "Facility").

12. On ___(Date)___, representatives of the ___(EPA Region, State or Tribe)___, duly authorized to conduct inspections under the authorities of Section 8 and Section 9 of FIFRA, 7 U.S.C. §§136*f* and136*g*, conducted inspections at Respondent's Facility.

13. During the inspections, the ___(EPA Region, State or Tribe)___inspectors collected a sample package of ___(Product Name)___, EPA Reg. No.: _____, from a sealed case on site which included the following label language:

    a. "For wiping hard non-porous environmental surfaces and patient care equipment".
    b. "Suggested areas of usage: Medical, Dental and Laboratory Counters, Exam Tables, Carts, Point of Care Equipment, Telephone, Sink Tops."

14. During the inspections, the ___(EPA Region, State or Tribe)___inspectors also collected a sample package of ___(Product Name)___ from a sealed case on site which included label language similar to the EPA registered ___(Product Name)___ product, EPA Reg. No.: _____, including the following:

    a. "Diluted Bleach Wipes for Hard Non-Porous Surfaces & Patient Care Equipment".
    b. "Suggested areas of usage: External cleaning of dialysis machines, chairs and equipment, as well as, laboratory counters, exam tables and sink tops."

15. According to the ___(Date)___, ___(EPA Region, State or Tribe)___inspection report, the ___(EPA Region, State, or Tribe)___ inspectors presented an ___(Company Name)___ officer with a printout from the ___(Company Name)___ website during the inspection that contained multiple disinfection claims in connection with ___(Product Name)___.

16. In a letter addressed to ___(EPA Region, State or Tribe)___dated the same day of the inspection, the same ___(Company Name)___officer stated that any reference to disinfection in connection with ___(Product Name)___ on the ___(Company Name)___ website was an error and would be removed.

17. As of ___(Date)___, ___(Company Name)___website included the following language in connection with its ___(Product Name)___:

    a. At ___(Company's Web Site URL)___ characterization of the product as a "Surface Disinfectant[ ]".
    b. At ___(Company's Web Site URL and subpage URL)___ the statement: "This pre-diluted, ready to use wipe meets the CDC Recommendations and OSHA requirements,

while being consistent with many medical equipment manufacturers' recommendations for surface decontamination".

c. At ___(Company's Web Site URL)___, the statements:
   (i). "___(Product Name)__ meet the CDC Recommendations and OSHA requirements (1:100 dilution is consistent with many medical equipment manufacturers' recommendations)".
   (ii). ___(Product Name)__ reduce the risk of cross contamination . . . and eliminate stability problems associated with bleach buckets, or diluted spray".
   (iii). a "Stability of Bleach" table illustrating the concentration of bleach over thirty (30) minutes of exposure.
   (iv). "APPROPRIATE FOR THE FOLLOWING MARKETS: Medical & Health Care Labs, Dialysis, Long Term Health Care, Acute Hospital, Dentistry, Ambulatory Care, Veterinary".

d. At ___(Company's Web Site URL)___, the statements:
   (i). "Would you like a convenient, time saving method for surface contamination?".
   (ii). ___(Product Name)__ meet the CDC Recommendations and OSHA requirements (1:100 dilution is consistent with many medical equipment manufacturers' recommendations)".
   (iii). ___(Product Name)__ reduce the risk of cross contamination . . . and eliminate stability problems associated with bleach buckets, or diluted spray".
   (iv). a "Stability of Bleach" table illustrating the concentration of bleach over thirty (30) minutes of exposure.
   (v). "APPROPRIATE FOR THE FOLLOWING MARKETS: Medical & Health Care Labs, Dialysis, Long Term Health Care, Acute Hospital, Dentistry, Ambulatory Care, Veterinary".
   (vi). procedures for use for "Decontamination of Surfaces".
   (vii). under "CDC Guidelines and Recommendations for 1:100 Diluted Bleach Solution":

> **Environmental Infection Control of Healthcare Facilities- June 2003**
> "If the surface is nonporous …and sodium hypochlorite solution is used, a dilution of 1:100 for decontaminating assuming that A) the worker assigned to clean the spill is wearing gloves and other personal protective equipment to the task, B) most of the organic matter of the spill has been removed with absorbent material and C) the surface has been cleaned to remove residual organic matter."

Recommendation for Preventing Transmission of Infections among Chronic Hemodialysis Patients MMWR50 (RR05); 1-43
"Intermediate level disinfection kills bacteria and most viruses and is accomplished by using a 1:100 dilution of bleach (300-600 mg/L free chlorine). For a blood spill, immediately clean the area with a 1:100 dilution of household bleach."
Draft Guideline for Disinfection and Sterilization in Healthcare Facilities HICPAC 2/20/2002
"If sodium hypochlorite solutions are selected use a 1:100 dilution (500 ppm available chlorine) to decontaminate nonporous surfaces after cleaning a small spill of either blood or OPIM [other potentially infectious material]."
Guideline for Infection Control in Dental Healthcare Settings - 2003, 2003MMWR (RR17)
"Sodium hypochlorite is an inexpensive and effective intermediate level germicide. Concentrations ranging from 500 ppm to 800 ppm of chlorine (1:100 dilution of 5.25% bleach and tap water, or approximately 1/4 cup of 5.25% bleach to 1 gallon of water) are effective on environmental surfaces that have been cleaned of visible contamination."

e. at ((Company's Web Site URL) the following statements:
   (i). procedures for use for "Disinfection of Surfaces".
   (ii). "Wipe the desired surface to be disinfected".
   (iii). under "CDC Guidelines and Recommendations for 1:100 Diluted Beach Solution":

Environmental Infection Control of Healthcare Facilities- June 2003
"If the surface is nonporous …and sodium hypochlorite solution is used, a dilution of 1:100 for decontaminating assuming that A) the worker assigned to clean the spill is wearing gloves and other personal protective equipment to the task, B) most of the organic matter of the spill has been removed with absorbent material and C) the surface has been cleaned to remove residual organic matter." (for more detailed information click here)

Recommendation for Preventing Transmission of Infections among Chronic Hemodialysis Patients MMWR50 (RR05); 1-43
"Intermediate level disinfection kills bacteria and most viruses and is accomplished by using a 1:100 dilution of bleach (300-600 mg/L free chlorine). For a blood spill, immediately clean the area with a 1:100 dilution of household bleach." (for more detailed information click here)

Draft Guideline for Disinfection and Sterilization in Healthcare Facilities HICPAC 2/20/2002
"If sodium hypochlorite solutions are selected use a 1:100 dilution (500 ppm

available chlorine) to decontaminate nonporous surfaces after cleaning a small spill of either blood or OPIM [other potentially infectious (for more detailed information click here)
material]."

Guideline for Infection Control in Dental Healthcare Settings - 2003, 2003MMWR (RR17)
"Sodium hypochlorite is an inexpensive and effective intermediate level germicide. Concentrations ranging from 500 ppm to 800 ppm of chlorine (1:100 dilution of 5.25% bleach and tap water, or approximately 1/4 cup of 5.25% bleach to 1 gallon of water) are effective on environmental surfaces that have been cleaned of visible contamination." (for more detailed information click here)

18. At (Company's Web Site URL), (Product Name) "09301-100 (Product Name) Singles 1:100 - Quantity: 100 pkgs per Box" and "09302-50 (Product Name) Doubles 1:100 - Quantity: 50 pkgs per Box" are available to the public for online purchasing.

19. Together, the language described in paragraphs 14 and 17, above, claim, state, or imply that (Product Name) can or should be used as a pesticide.

20. (Product Name) is a pesticide, as defined in Section 2(u) of FIFRA, 7 U.S.C. §136(u), and 40 C.F.R. §§152.3 and 152.15.

21. (Product Name) is not registered with EPA as a pesticide, and has never been so registered.

22. Respondent owns, controls and/or has custody of the (Product Name) described herein, and has sold or distributed or intends to sell or distribute such product to other persons, in violation of Sections 12(a)(1)(A) of FIFRA, 7 U.S.C. §§136*j*(a)(1)(A).

III. ORDER

23. This Order requires Respondent to stop the sale, use, or removal of unregistered pesticides owned, controlled, or in the custody of Respondent at or from an establishment located at or in the vicinity of (Establishment Address), or at or from any other establishment wherever located. Respondent shall undertake all actions required by this Order, and comply with all requirements of this Order, including any subsequent modifications to this Order.

24. EPA hereby orders the Respondent to stop the sale, use or removal of (Product Name).

25. This Order shall pertain to all quantities (in all packaging types and sizes) of (Product Name), owned, controlled, or in the custody of Respondent or any parties acting as

agents for Respondent wherever they may be located. The product covered by this Order shall not be distributed, sold, offered for sale, held for distribution, held for sale, held for shipment, shipped, delivered for shipment, released for shipment, received and (having been so received) delivered or offered for delivery, moved, used or removed for any reason, other than in accordance with the provisions of this Order or any such further order as may be issued by EPA in connection with the pesticide product identified in this Order.

26. Violation of the terms or provisions of this Order may subject Respondent and/or any responsible individuals to civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. §136*l*.

27. The issuance of this Order shall not act as a waiver by EPA of any enforcement or other authority available to EPA under FIFRA or any other federal statute.

28. This Order shall be effective immediately upon receipt by Respondent or any agents of Respondent.

29. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified, in writing, by EPA.

30. For instructions as to the ultimate disposition of all existing stocks of (Product Name), and for technical assistance regarding any matter addressed in this Order, please contact:

(Regional Pesticide Staff Person Name)
(Region Division / Branch, and Mail Code)
U.S. EPA, Region ???
(Regional Address)
Phone: ( ) #
Fax: ( ) #
E-mail:

31. For questions regarding legal matters relating to this Order, you or your attorney may contact:

(ORC Attorney's Name), Esq. (Mail Code)
(Division / Branch)
U.S. EPA, Region ???
(Regional Address)
Phone: ( ) #
Fax: ( ) #
E-mail:

_____ _____

Date (Name of EPA Director), Director (Name of Division)

CHAPTER FIFTEEN
RECALLS

CONTENTS

Statutory Authority 2
Voluntary Recall 2
Mandatory Recall 2
Contents of Recall Plan 3
Objectives 3
Recall Procedures 3
Process 3
Levels of Recalls 4
Notification to the Company 4
Inspection Procedures 4
Initial Visit to Company(s) Identified in the Recall 5
Follow-Up to Recall 5
Follow-Up after Completion of Recall 5
Reporting 5
Initial Recall Report 5
Interim Reports 6
Final Recall Reports 6

RECALLS

STATUTORY AUTHORITY

FIFRA section 19(b) authorizes the recall of products if the registration of a pesticide has been suspended or canceled under section 6 or when the Administrator finds that a recall is necessary to protect health or the environment.

VOLUNTARY RECALL

If, after determining that a recall is necessary, the Administrator finds that voluntary recall by the registrant and others in the chain of distribution may be as safe and effective as a mandatory recall, the Administrator shall request the registrant of the pesticide to submit, within 60 days of the request, a plan for the voluntary recall of the pesticide. If such a plan is requested and submitted, the Administrator shall approve the plan and order the registrant to conduct the recall in accordance with the plan unless the Administrator determines, after an informal hearing, that the plan is inadequate to protect health or the environment.

MANDATORY RECALL

If, after determining that a recall is necessary, the Administrator does not request the submission of a voluntary recall plan or finds such a plan to be inadequate, the Administrator shall issue a regulation that prescribes a plan for the recall of the pesticide. A regulation issued under this paragraph may apply to any person who is or was a registrant, distributor or seller of the pesticide or any successor in interest to such a person.

A regulation prescribing a mandatory recall may require any person that is subject to the regulation to:

- Arrange to make available one or more storage facilities to receive and store the pesticide to which the recall program applies and inform the Administrator of the location of each such facility.
- Accept and store at such a facility those existing stocks of such pesticide that are tendered by any other person who obtained the pesticide directly or indirectly from the person that is subject to such regulation.
- On the request of a person making such an offer, provide for proper transportation of the pesticide to a storage facility.
- Take such reasonable steps as the regulation may prescribe to inform persons who may be holders of the pesticide of the terms of the recall regulation and how those persons

may tender the pesticide and arrange for transportation of the pesticide to a storage facility.

CONTENTS OF RECALL PLAN

A recall plan established under FIFRA section 19(b) shall include:

- The level in the distribution chain to which the recall is to extend and a schedule for recall.
- The means to be used to verify the effectiveness of the recall.

Failure to comply with a voluntary/mandatory recall may result in the issuance of a stop sale, use or removal order to the consignees of the pesticide in question.

OBJECTIVES

The recall program is designed to remove any violative product from the market as expeditiously as possible. Recalls may be initiated in any case in which the available information indicates that the product is (1) potentially hazardous when used as directed or (2) ineffective for the purpose(s) claimed in the registration. A product will be considered for recall when, among other things, its use as directed would likely result in the following:

- Economic or physical injury to the user or handler of the product.
- Injury to animals or plants where direct application is made.
- Injury resulting from illegal residues.
- Injury to fish or wildlife.
- Other adverse effects on the environment.

A recall may be made after the cancellation by EPA of a product due to lack of existing tolerance, environmental damage caused by a pesticide's labeled uses, or EPA actions taken under the Food Quality Protection Act of 1996 during a pesticide's registration or re-registration, such as cancellation due to harm to workers, or human health risk analysis.

RECALL PROCEDURES

PROCESS

The following summarizes the steps by Office of Pesticide Programs and the Office of General Counsel in the recall process:

- Identify the violation and develop evidence to support the violation and the hazard presented.
- Prepare a complete description of the material to be recalled and the level in the distribution chain to which the recipient will be requested to remove the product.
- Prepare and issue the recall.

Inspectors participate in the process by monitoring the quantities returned from each location and by monitoring the disposition of all returned material.

LEVELS OF RECALLS

The level of recall refers to the point in the distribution chain from which the product is to be recalled. The determination of that point is based on the potential hazard, use pattern and distribution pattern of the product. The levels of recall can extend to the following:

- Pesticide products under the registrant's control.
- Products in the chain of distribution not under the control of the registrant.
- User-level recalls. Recalls at this level generally are requested only in cases where there is a very serious hazard to human health or the environment.

NOTIFICATION TO THE COMPANY

A notification will be sent to the registrant's headquarters ordering a recall. The letter will include:

- A brief summary of why EPA is requesting a recall.
- A request that the company provide EPA with the amount and location of product that is being recalled (if it is known).
- A request that EPA be provided with information on all steps taken in connection with the recall and an accounting of the amount that was actually recalled.

Additionally, EPA may provide draft recall letters for the company to send to their primary and secondary distributors and for those distributors to send to their customers.

The company is encouraged to contact EPA and discuss the notice. In urgent cases, EPA will initially notify the company by telephone and/or facsimile.

INSPECTION PROCEDURES

After the company has received notification of recall from EPA, an inspector will be assigned to monitor the recall. EPA will provide the inspector with the recall notification. In some instances,

the inspector may receive a strategy from EPA's Office of Enforcement and Compliance Assurance for monitoring the recall. If OECA has not provided a strategy, the EPA regional supervisor and the inspector must develop their own strategy before proceeding. The inspector will receive a copy of any recall agreement between the registrant(s) and EPA. Each recall is unique. The inspector must review and understand the terms of the recall before conducting an inspection.

INITIAL VISIT TO COMPANY(S) IDENTIFIED IN THE RECALL

An initial visit must be planned to occur approximately 30 days after the date of the recall notification. The 30-day time period provides adequate time for the company to respond to the recall notification and decide upon a course of action. The inspector must review the progress of the recall with the responsible company official and obtain copies of documents, records and correspondence used by the company in the recall. If the inspector discovers that the terms of the recall are not being met (e.g., failure to notify distributors as required), the inspector must document the noncompliance. This may be accomplished by photocopying appropriate documents or taking statements from knowledgeable persons.

FOLLOW-UP TO RECALL

The inspector may conduct interim visits to the company or receive status reports from the company to document how the recall is proceeding.

FOLLOW-UP AFTER COMPLETION OF RECALL

Once EPA receives information that the inspector located all available pesticide products and that the products were either returned or held, the regional EPA pesticide supervisor may decide to visit a select number of consignees to determine the effectiveness of the recall. Each consignee visited must be asked whether the firm received a recall letter, whether any of the pesticide products in question was on hand and, if so, whether the company complied with the recall letter. The inspector should document responses.

REPORTING

All inspection reports must be provided to the regional supervisor for evaluation and a summary of the inspection reports must be forwarded to EPA headquarters.

INITIAL RECALL REPORT

The initial visit report must be a narrative that reflects the company's efforts to implement the recall and will include:

- When appropriate, a list of consignees to whom the recall letters were mailed and the date(s) sent.
- Any documentation obtained during the visit.

INTERIM REPORTS

Interim reports must be submitted on: (1) a regular basis as required by the compliance strategy, and (2) whenever any new information becomes available.

FINAL RECALL REPORTS

The final recall report is the inspector's narrative summarizing actions taken by the company and must be submitted as soon as the recall is completed in accordance with the recall notification. This report must include the following information:

- Name of the product being recalled.
- EPA Registration Number of the product being recalled.
- Batch number(s) of the product being recalled.
- Name, address and contact for the company that received EPA's letter requesting the recall of the product.
- Action taken by the company, such as:
    - Number of consignees the company had and number of consignees they contacted.
    - Actual amount of the product the company distributed to consignees.
    - Amount of products the consignees still have in their control.
    - Number of consignees that returned product.
    - Total amount of product returned for all of the consignees.
- What the company did with the product. (Did they dispose of it or reuse it?)
- Which consignees the inspector visited; dates of inspections; and documented discrepancies.

CHAPTER SIXTEEN
INSPECTION REPORTS AND SUPPORTING DOCUMENTATION

CONTENTS

Introduction 2
Purpose of Written Reports 2
Communicate 2
Provide a Basis for Compliance Determination/Action 2
Releasability of Written Reports and Records 3
Five Steps in Writing a Narrative Report 3
Step 1—Plan 3
Step 2—Organize the Material 3
Step 3—Write 3
Step 4—Evaluate 4
Step 5—Rewrite 4
Essentials of A Good Report 4
CBI Considerations 5
Report Format 6
Supporting Documentation 6
Field Notebooks 6
Statements 7
Photographs 8
Drawings and Maps 9
Printed Matter 9
Mechanical Recordings 9
Exhibit 16-1: FIFRA Establishment Inspection Report Example 10
Exhibit 16-2: FIFRA Use/Misuse Investigation Report Example 12

INSPECTION REPORTS AND SUPPORTING DOCUMENTATION

INTRODUCTION

Information gathered and presented by inspectors is essential to the success of the enforcement program. The inspector must be able to prepare clear, objective and well-documented written inspection reports.

PURPOSE OF WRITTEN REPORTS

COMMUNICATE

The main purpose of a written inspection report is to clearly and concisely communicate a complete and factual record of the inspection process, observations and results to the reader, from the opening conference, through the inspection/collection of samples, to the closing conference. To communicate effectively, the report must be a complete and accurate record of what was discovered and what occurred during the inspection. The report shall not contain any opinions of the inspector and shall not make any conclusions of law.

PROVIDE A BASIS FOR COMPLIANCE DETERMINATION/ACTION

The inspection report must contain information and documentation about the inspection that will enable a case review officer to determine:

- the facility's compliance with FIFRA and
- that the inspector followed statutory requirements for:
    - presenting credentials,
    - issuing a Notice of Inspection, containing a reason for the inspection,
    - collecting evidence and issuing a Receipt for Samples.

If enforcement action is warranted, the inspection report must contain all the elements necessary to support any alleged violations. For example, if an inspector discovers an unregistered pesticide, the inspector must gather the complete pesticide label (i.e., front and back panels and any associated booklets or labeling materials) and/or take high resolution digital photographs of the product, and collect shipment and/or distribution information for the product, along with any other relevant information about the product and include this

information in the inspection report. If an inspection report is not complete or accurate, EPA may have to expend additional time and resources.

RELEASABILITY OF WRITTEN REPORTS AND RECORDS

The regulated community sometimes requests copies of written reports and records associated with inspections. The Freedom of Information Act (FOIA) governs the disclosure of information to industry and the public and is discussed in Chapter 1. Federal inspectors, as well as state or tribal inspectors performing federal inspections, shall not release any notes, documents, reports, etc. obtained or prepared in connection with a FIFRA inspection until such time as authorized by EPA. EPA inspectors should refer to the "Interim Policy on Inspection Report Timeliness and Standardization", June 29, 2018 issued by OECA or any subsequent final policy.

FIVE STEPS IN WRITING A NARRATIVE REPORT

STEP 1—PLAN

By planning how facts must be presented in the inspection report prior to the inspection, the inspector can improve the quality of the inspection report as well as the inspection itself. It should be noted that some elements that will need to be included in or with the report (i.e., samples analysis) may not be available at the time of report preparation. Do not delay preparing the report while waiting for sample analysis. Sample analysis can be added as an exhibit to the report when it becomes available.

STEP 2—ORGANIZE THE MATERIAL

All information gathered during the inspection must be reviewed for relevance and completeness. This includes inspection report forms, field notebooks and checklists. The field notebook and/or inspection checklists are useful tools for developing the narrative report, but cannot replace a narrative report. Any identified gaps in the information must be resolved by follow-up telephone calls or follow-up inspections. The material must then be organized in the order that it will be presented in the report.

STEP 3—WRITE

While writing the inspection report, keep the following in mind:

- The inspection report should be a complete record of what occurred at the inspection, including conversations that took place, documentation that was collected and physical samples that were collected. Photographic evidence should be included when appropriate.

- Just report the facts as to what was observed. Do not include opinions or conclusions of law. Keep the reader in mind. When preparing an inspection report, assume that the reader knows nothing about the case except what is in the report. The report must construct a complete and accurate picture of the entire inspection, step-by-step.
- The report should be peer-reviewed before it is finalized.

STEP 4—EVALUATE

After writing the report, review the report from the viewpoint of the reader and answer the following questions:

- Does it answer the questions—who, what, when, where, why and how?
- Is each asserted fact supported, with a citation provided, by a document, picture, sample, recorded observation or statement from an individual?
- Is it fair, concise, complete, accurate and logical? Is any part ambiguous?
- Does it communicate clearly?
- Is there any other information needed to fulfill the purpose of the investigation?
- Can supervisors and reviewers make appropriate decisions based on this report?
- Are any further inquiries necessary?

Proofread the report to check for inconsistencies, unnecessary repetition, tone, omissions and typographical errors.

STEP 5—REWRITE

Correct those portions of the narrative that were identified as needing improvement.

ESSENTIALS OF A GOOD REPORT

- **Fairness**—The report must be objective, impartial, unbiased and unemotional. Convey facts so they speak for themselves. Avoid rumors, gossip, or offensive remarks or language. To test for fairness, read the material aloud to ensure the report is conveying the proper tone for the reader and the purpose of the report.
- **Accuracy**—The information must be stated precisely and accurately in plain language. The inspection report must under no circumstances include the inspector's conclusions regarding compliance or noncompliance. The goal is to present the facts clearly. If the inspector wants to communicate certain opinions to the reviewer, these opinions must be contained in a memorandum to the file or legal office separate from the inspection report and be marked "enforcement confidential" and "attorney-client privileged."

These memoranda are usually "to the file" and identified as "Not for FOIA release." In an enforcement case, the entire inspection report is subject to discovery by the opposing side. If conclusions of law or opinions are in the report, it may weaken the inspector's credibility. In addition, the inspector may have been wrong about a violation. Attorney-client privilege typically protects a separate memorandum of findings or conclusions from discovery.

- **Completeness**—Include all information observed. Something that may seem irrelevant at the time of the inspection may prove relevant later on. All known facts should be reported either in the text or as an attachment, so that no further explanation is needed. The report must answer the questions "who, what, when, where, why and how." Each asserted fact should be supported, with a citation provided, by a document, picture, sample, recorded observation or a statement from an individual.
- **Sources of evidence**—Always report the source of information (including their job title) and document where samples were obtained.
- **Attachments**—The report will consist of a narrative portion with appropriate attachments that are labeled and consistently referenced in the report so that they are easy to follow and find. The attachments will support and document that the inspector followed statutory requirements and will be used as the basis to make a decision as to a facility's compliance status. Always reference attachments parenthetically in the narrative portion of the report and consecutively number in the order mentioned.
- **Facts indicating weaknesses in the case**—Explanations from the individuals being interviewed or important facts that point to weaknesses in the case should not be omitted. Subsequent disclosure of facts indicating weaknesses that were known by the report writer but not disclosed may compromise any potential enforcement action. Disclosure of any potential weaknesses in the report will give reviewers an opportunity to determine the appropriate a course of action.
- **Conciseness**—Concise writing includes facts, details and necessary explanation, but is free of all that is elaborate or non-essential. Conciseness is not what is said, but how it is said. Use short sentences with active verbs and paragraphs whenever possible.
- **Clarity and logical presentation**—The report must be written clearly in order to avoid misinterpretations. Writing takes time and effort. Order thoughts and arrange them logically, and select the words that will best convey the thoughts to the reader.

CBI CONSIDERATIONS

An inspector may encounter Confidential Business Information (CBI) during an inspection. Examples of CBI may include:

- Establishment's pesticide production records,

- Batch records,
- Product formulation, and/or
- Annual pesticide production reports.

Those portions of the report that contain CBI must be treated in accordance with FIFRA CBI procedures. See Chapter 1 for more information on CBI procedures.

REPORT FORMAT

The inspection report consists of a narrative report with several attachments. See Exhibits 16-1 and 16-2 for examples of inspection report outlines.

SUPPORTING DOCUMENTATION

In addition to physical samples, documentary support is necessary for an enforcement case. These documents may include field notebooks, statements, copies of records, photographs, drawings and maps, printed matter and mechanical recordings. Establishing a chain of custody is just as important for supporting documentation as it is for pesticide product sampling and residue and environmental sampling. The chain of custody establishes where the document has been and how it has been treated since it was collected. See Chapter 6 (Pesticide Product Sampling) and Chapter 7 (Residue and Environmental Samples) for additional information.

FIELD NOTEBOOKS

The field notebook is the core of all inspection documentation. The field notebook (preferably bound) is part of the Agency's files and is not the inspector's personal record. Notebooks must be held indefinitely as supporting documentation to the inspection file. The field notebook is intended to provide accurate and inclusive documentation of all inspection activities and to provide a basis for written inspection reports. Inspectors shall record only facts and pertinent observations using objective language, free of personal feelings.

It is essential for the inspector to keep detailed records of inspections, investigations, samples collected, etc. to serve as an aid in writing reports and giving testimony. The following types of information shall be included in the field notebook:

- **Observations**. Record all conditions, practices and other observations that will be useful in preparing the inspection report or will contribute to establishing valid evidence.
- **Unusual conditions and problems**. Note and describe in detail any unusual conditions and problems encountered during the course of the inspection visit.

- **General information**. List names and titles of personnel encountered and the activities they perform, along with any statements they may have made and other general information.

Inspectors should either have separate field notebooks for each inspection or clearly identify each inspection separately in the field notebook so that copies of the notes applicable to the inspection can be included in the case file should enforcement action be taken.

STATEMENTS

An inspector should obtain statements from persons having knowledge of the facts pertinent to a potential violation. Use EPA Statement Form 3540-42 (Exhibit 1-1). The purpose of obtaining a statement is to have a written record containing factual information to be used to determine if there has been a violation or to document an alleged violation. Statements are similar to affidavits except that the statement is not made under oath. The following procedures and considerations may be helpful in developing a proper statement:

- Determine the need for a statement. Will a statement provide useful factual information that will help to determine whether a violation occurred or to show a violation occurred? Is the person making the statement qualified to do so by having personal knowledge?
- Identify the person making the statement (name, position, address, etc.).
- Explain why the person is qualified to make the statement.
- Use a simple narrative style (avoid stilted language).
- Narrate the facts in the words of the person making the statement (use the first-person singular).
- Present the facts in chronological order, unless the situation calls for some other arrangement.
- Read the statement to the person (preferably in the presence of a witness) and make any necessary changes, initialing all corrections or changes.
- Ask the person making the statement to write a brief concluding paragraph indicating that he/she read and understood the statement. This safeguard will counter a later claim that the person did not know what he/she was signing.
- Have the person sign the statement. The inspector must also sign and date the statement. Be sure to provide a copy of the statement to the signer, if requested.
- If he/she refuses to sign the statement, elicit a verbal acknowledgment that it is true and correct, and then record that acknowledgement on the statement. The inspector should initial or sign the statement nearby the written verbal acknowledgement, and also sign the statement in the appropriate block at the bottom of the form.

Note that FIFRA inspectors may not take affidavits or statements under oath or affirmation except where the inspector is authorized under state law to take affidavits or statements under oath or affirmation (e.g., a notary).

PHOTOGRAPHS

Photographs are valuable as evidence as they provide an objective record of the conditions at the time of inspection. EPA encourages inspectors to use high-resolution digital photography to document the products and devices observed during inspection. When taking photographs during an inspection, follow these steps:

- Follow the guidelines in the EPA Digital Image Guidance for EPA Civil Inspections and Investigations.
- All photos should be recorded on the EPA Photo Log, EPA Form 3540-43 (see Exhibit 1-1).
- Chain-of-custody procedures apply to photos. Keep all digital and/or original hard copy photos in a secure location and do not alter photos in any way. If an alteration is necessary (cropped, enlarged, etc), save a copy of the original for reference.
- Digital photographs are preferable, but if photographs are taken on film, the inspector must immediately identify the location, date, inspector's initials and related sample number (if applicable). The field notebook should identify the order in which photographs are taken and, once developed, the same information should be written on the back of the photo itself.
- It is sometimes useful to photograph a subject from a point that will indicate the location and direction of the subject. The addition of an object of known size, such as a person, car, coin or ruler will help indicate the size of the subject. This is known as using a reference by which to judge size, distance or location.
- Do not take photographs of written records or reports that are or may be considered CBI. However, pesticide products, product labels and establishments are generally not considered CBI and not subject to confidentiality claims. Although EPA has the authority to take photographs during inspection, if there is sensitive or confidential material in the establishment, the inspector shall request that pesticides be moved to a non-sensitive area of the establishment (such as the loading dock) for photographs.
- Videography is also appropriate in enforcement documentation. The same recommendations apply to videography as apply to photography.

DRAWINGS AND MAPS

Schematic drawings, maps, charts and other graphic records may be useful in documenting a violation. Drawings and maps should be simple and free of extraneous details. Basic measurements must be included to provide a scale for interpretation and compass points must be included.

All drawings, maps, etc. must be identified with the inspector's initials, the date, sample number and any other pertinent information (e.g., “not drawn to scale”). It would be useful to identify the source of any commercial map, chart or other graphic record.

PRINTED MATTER

Brochures, literature, labels and other printed matter can provide important information regarding a firm's conditions and operations. These materials may be collected as documentation. All printed matter must be identified with date, inspector's initials and related sample numbers.

MECHANICAL RECORDINGS

Records produced electronically or by mechanical apparatus can be used as evidence. Follow normal chain-of-custody procedures in collecting electronic records.

EXHIBIT 16-1: FIFRA ESTABLISHMENT INSPECTION REPORT EXAMPLE

Establishment Name
Street Address
(Mailing Address, if different)
City, State Zip Code

Date of Inspection

Performed by:
U.S. Environmental Protection Agency (or state/tribal government)
Office/Division/Branch
Address
City, State Zip Code
FIFRA Establishment Inspection Report
[Inspection No. __ FIFRA _____]

I. Company Information

A. Company Name
B. Establishment Registration Number
C. Responsible Official(s) [Include full name, title and telephone number]
D. Type of Ownership

II. Date of Inspection

III. Participants

A. Company
B. U.S. EPA [or state/tribe]

IV. Inspection Objectives

V. Company Background

VI. Inspection Summary

A. Opening Conference
B. Inspection Observations and Sample Collection
C. Closing Conference

VII. Index of Attachments

A. Standard Forms

1. FIFRA Notice of Inspection
2. Receipt for Sample
3. Chain of Custody

B. Evidence

1. Photographs
2. Copy of Label on Physical Sample
3. Copy of Records
    a. Records of Inbound Shipments
    b. Production Records
    c. Inventory Records
    d. Shipping Records
4. Product, Device or Bin Labels/Labeling
5. Statements
6. Laboratory Analysis

_____ _____

Inspector's Name and Title Date

EXHIBIT 16-2: FIFRA USE/MISUSE INVESTIGATION REPORT EXAMPLE

Name of Suspected Violator
Street Address
(Mailing Address, if different)
City, State Zip Code

Date of Inspection

Performed by:
U.S. Environmental Protection Agency (or state/tribal government)
Office/Division/Branch
Address
City, State Zip Code
FIFRA Use Inspection Report
[Inspection No. __ FIFRA _____]

I. Participants

   A. Complainant/Address/Telephone Number

   B. Certified Applicator/Company Name/Address/Telephone Number

   C. Suspected Violator/Company Name/Address/Telephone Number

II. Circumstances

   A. What Happened and Where

   B. How and What was Reported

III. Chemical Information (EPA Reg. No., brand name, specific language on the label that is relevant to the investigation)

IV. Investigation

   A. Investigator's Activities in Sequential Order

   B. Statements (who, when and what)

   C. Mapping/Photographs (where, what)

   D. Sampling (what type of sample(s) were collected and where, what analyzed for)

   E. Records (sales or application)

   F. Weather Data (what records were obtained, from whom, date obtained, what do the records show)

V. Attachments

CHAPTER SEVENTEEN
ENFORCEMENT

CONTENTS

Civil Enforcement 2
Hearings 2
Prehearing Preparation 2
Serving as a Witness in a Hearing 3
The Direct Examination 4
Cross Examination 4
Criminal Enforcement 5
The Criminal Provisions of FIFRA 6
FIFRA's Relationship to Other Federal Criminal Laws 6
Special Attention to Defendant's Rights 6
Criminal Enforcement at EPA 7
Recognizing Potential Criminal Violations 8
Searches 9
Compelling the Production of Information 10
Discovery 11
Initiating Criminal Investigations 11
Conducting a Criminal Investigation 11
Security of Criminal Investigations 12
Parallel Criminal and Civil Proceedings 13
Compliance with the Jencks Act 13
Participation in Grand Jury Investigations 14

ENFORCEMENT

If violations of law are detected during an inspection and documented properly, EPA may initiate a civil or criminal enforcement action. EPA typically initiates a civil enforcement action by filing an administrative complaint with the Office of Administrative Law Judges, pursuant to the procedural rule set forth in 40 C.F.R. Part 22. EPA may also initiate a criminal action in federal court to address knowing and willful FIFRA violations. This chapter will focus on the role of the FIFRA inspector during enforcement proceedings.

CIVIL ENFORCEMENT

HEARINGS

At a FIFRA enforcement hearing, the inspector may serve several roles. As part of the enforcement team, the inspector's knowledge is critical in determining the violations and preparing documents for hearings. Most importantly, the inspector may be called upon to serve as a fact and/or expert witness in civil and criminal proceedings and may be required to provide testimony and documents in support of EPA's enforcement action.

PREHEARING PREPARATION

Any inspection may result in an enforcement action. Therefore, inspectors should approach each and every inspection as if it will go to trial—scrupulous attention to procedure, highly professional conduct and detailed, solid documentation. To prepare for a hearing, the inspector may be asked to:

- Ensure the inspection file is complete and organized. Go over the facts of the case with the assigned attorney before any complaint is filed. If you suspect there are any problems with the potential evidence in the case, bring those problems to the attention of your attorney right away.
- Meet with the assigned attorney to determine your involvement in the hearing and to go over expected testimony. Ask what the attorney intends to prove by your testimony, and how the attorney intends to use any documents or items of potential evidence collected during the inspection. Ask any questions of the attorney at the earliest opportunity. It will be too late to find out what you are supposed to do once the hearing begins.
- Clear your calendar for the days you will be needed as a witness. Your attendance will be mandatory.

SERVING AS A WITNESS IN A HEARING

Demeanor matters when serving as a witness. An inspector's demeanor must reflect the serious nature of the proceeding. Here are some tips:

- Do not discuss the case with anyone that is not part of the EPA team. Hold discussions among the EPA team only when you are in a location where no one else can overhear.
- Do not whisper, talk or cause any disturbances in the courtroom.
- Sit in the seats provided for the spectators but as near the front as possible since the EPA attorney may need to consult with you during the hearing.
- Do not bring magazines or newspapers into the courtroom. The inspector should listen intently to the proceeding while in the courtroom.
- Do not react to testimony given by other witnesses or at statements made by the defense attorney. Negative reactions make the witness appear unprofessional.
- Be on time and be available immediately when called to testify.
- Expect to stay in the courtroom when not testifying to listen to the testimony of other witnesses. It may trigger a forgotten fact, a memory or an interpretation. Note that you may be instructed to leave the courtroom and, if so, leave calmly.
- Do not interrupt the attorney while the hearing is in progress. If you must convey information, write it down and hand him/her the note. He/she will look at it when he/she can concentrate. If necessary, he/she can ask for a recess and talk to you.
- When in doubt about anything, consult the government attorney.
- When called to the witness stand go directly to the desk of the clerk of the court (or the judge) to be sworn in.
- The judge or clerk will ask you to swear that your testimony will be true. The answer is "yes" or "I will" depending on how the oath is worded. If you cannot in good conscience "swear under oath," state that you wish to "affirm" your testimony. Inform the government attorney of this prior to the hearing.
- Your testimony will be taken down by tape recording or manual transcription by the court reporter. Therefore, answers to questions must be made verbally rather than by shaking or nodding your head. Dimensions and directions must be given verbally rather than demonstrated.
- Always pause before answering clearly and distinctly. Pausing gives the attorney time to object to the question, if necessary.
- The judge may ask you a question from the bench. Address him/her as "Your Honor" and answer the question.

- You must be objective and professional. A calm demeanor projects confidence. Therefore, do not show hostility toward the defendant or the opposing counsel.
- If you need to use acronyms or technical terms, make sure you explain what they mean. You must make sure your attorney knows the terms before the hearing and that the court reporter knows what they are and how to spell them. Try to use everyday language when possible.
- Always tell the truth.
- Answer only the question asked. Do not volunteer additional information.
- Do not be afraid to say, "I do not know," or "I do not understand the question," if indeed you do not know the answer. This answer must never be used to be evasive. You may be qualified as an "expert witness" but this does not mean you are infallible; you can only answer the questions to the best of your ability.
- Do not give personal opinions unless qualified as an expert witness.

THE DIRECT EXAMINATION

Direct examination is conducted by the EPA attorney. Before the hearing, the EPA attorney will prepare the inspector by reviewing every question you will be asked during direct examination and every answer you will give.

The EPA attorney will ask the witness to identify themselves and describe their connection to the case. This will "lay the foundation" for the witness's testimony. Inspectors will then be asked about their first-hand knowledge of pertinent facts in the case. This will establish the witness as a fact witness and will identify the intended subject of the testimony.

Most inspectors will serve as a fact witness and will testify to what they did, saw and heard. However, if the inspector will also serve as an expert witness, a foundation will be laid to establish the specialized knowledge or skills that qualify him/her as an expert. Typically, questions that will establish the requisite expertise will focus on education, training or experience.

CROSS EXAMINATION

Cross examination is conducted by opposing counsel. The purpose of cross examination is to cast doubt on the direct testimony. This can be done by attacking credibility, showing inconsistencies, attacking underlying facts and by attacking opinions, amongst other methods. The inspector should project a calm, professional demeanor and avoid being defensive. Under cross examination, you will be subject to more vigorous questioning than under direct examination. Special tips for cross examination:

- Opposing counsel may try to confuse you or get you angry. This is intentional. Remain calm, do not react and answer the question to the best of your ability.
- Opposing counsel may challenge your truthfulness, your credentials, your ability to do your job or your conclusions. This is intentional. Remain calm, do not react and answer the question to the best of your ability.
- Opposing counsel may ask compound questions (more than one question at a time) or rapid questions. Remain calm and answer at your own pace. You may ask for questions to be repeated or restated.
- Do not be argumentative.
- Opposing counsel will deliberately ask questions to elicit a "yes" or "no" answer. However, if you need to elaborate, do so.
- Opposing counsel may pose hypothetical questions that require you to give an opinion or draw a conclusion. As a fact witness (as opposed to an expert witness) you may not give opinions. Therefore, avoid answering hypothetical questions.
- Do not agree with the opposing attorney just to get him/her to stop badgering you.
- If the cross-examiner should misquote any of your earlier testimony when asking a question, you should correct them before answering the question.
- If you make an error while testifying, correct it at the first opportunity. If you discover the error after you have completed your testimony and have been dismissed as a witness, discuss the matter with the government attorney as soon as possible. If you have made an error, admit it and explain it, if possible.

CRIMINAL ENFORCEMENT

The mission of EPA's criminal enforcement program is to investigate, help prosecute and deter the most egregious environmental offenders. Our nation's environmental laws include criminal provisions that address knowing and negligent environmental violations. Criminal enforcement brings to bear the possibility of incarceration and monetary fines that are EPA's strongest sanctions.

FIFRA inspectors are among the pesticide enforcement personnel most likely to initially detect criminal environmental violations. Any FIFRA inspector who uncovers what he/she believes to be any type of criminal environmental offense must bring this fact promptly to the attention of their EPA supervisor and, in turn, notify the EPA criminal enforcement counsel of Special Agents. Many environmental criminal investigations and prosecutions can trace their beginnings to a single telephone call by an alert inspector.

The Federal Law Enforcement Training Center in Brunswick, Georgia, can provide special training for interested FIFRA inspectors (and other environmental technical personnel) involved in criminal investigations.

THE CRIMINAL PROVISIONS OF FIFRA

FIFRA section 14(b) makes the knowing violation of any provision of FIFRA punishable as a crime subject to criminal penalties consisting of fines and/or a term of imprisonment. More severe criminal penalties are provided for convicted defendants who are pesticide registrants, applicants for registration, pesticide producers and commercial applicators than for private pesticide applicators. See FIFRA sections 14(b)(1) and 14(b)(2).

FIFRA section 12 specifically lists the unlawful acts that are subject not only to civil and administrative enforcement, but also to criminal investigation and prosecution. A FIFRA inspector must be alert to the fact that the commission of any of these unlawful acts may potentially represent a criminal case.

FIFRA'S RELATIONSHIP TO OTHER FEDERAL CRIMINAL LAWS

Individuals and companies that commit environmental crimes often commit additional violations of the U.S. Criminal Code (Title 18), such as conspiracy, obstruction of justice, mail fraud and wire fraud. When these offenses are associated with alleged environmental crimes, EPA investigates and assists in the prosecution of such matters by the Department of Justice (DOJ). Criminal environmental conduct may also be prosecuted under one of the other environmental laws or one of the general criminal laws. For example, submission of false information as part of a pesticide registration may not only constitute a violation of FIFRA but also the federal false statement statute and conspiracy laws. See 18 U.S.C. Sections 1001 and 371, respectively.

Criminal activity involving pesticides may violate other environmental statutes enforced by EPA. For example, the unlawful disposal of pesticides may be a criminal violation of the Resource Conservation and Recovery Act (RCRA) or if the disposal was into a river, such conduct could amount to a criminal violation of the Clean Water Act (CWA). The prosecution team will decide under which statute to proceed and what other factors may be relevant, including the evidence available to establish an offense and the different penalty levels of the involved statutes.

SPECIAL ATTENTION TO DEFENDANT'S RIGHTS

Investigations of alleged criminal activities place even greater responsibilities on EPA's Special Agents. Because more severe penalties may be imposed on individuals convicted of violating the criminal provisions of environmental laws or other statutes, there are greater constitutional safeguards to protect their rights. Thus, it is of critical importance that all participants in criminal investigations be fully aware of these safeguards and conduct themselves accordingly. Special

Agents of the Criminal Investigation Division (CID) provide the necessary instructions and directions to the investigation team on these matters. The constitutional rights of defendants must be fully protected, from the beginning of a criminal investigation until it is completed, and established investigation procedures must be followed. The potential defendant may desire to conceal his or her criminal activities and, upon detection, frequently challenge to the procedures used to apprehend them and seize evidence of their criminal misconduct.

These challenges to the government's case principally stem from the Fourth Amendment's "Exclusionary Rule" which prohibits the use of evidence during the prosecution of a defendant whose constitutional rights were violated by the procedures used to collect that evidence. Also excluded is any information subsequently derived from improperly collected evidence. The procedures used by EPA's CID are designed to ensure protection of the defendant's rights and leave a documentary record of the investigation that will support admission of the resulting evidence into a prosecution.

Another frequent procedural challenge occurs when a suspect provides statements to a law enforcement officer after being taken into custody. The Special Agent must first issue a "Miranda Warning" and obtain a knowing waiver of such rights if the statements are to be admissible evidence. Defendants also have a right against self-incrimination. This means that a defendant can be silent and make the government prove its case. Thus, Special Agents are specially trained in their responsibilities relative to advising individuals of their constitutional rights during non-custodial and custodial interviews.

CRIMINAL ENFORCEMENT AT EPA

The Criminal Investigative Division (CID) staff is a part of the Office of Criminal, Enforcement, Forensics and Training (OCEFT) in Washington, D.C., with Special Agents operating out of field units at all regional offices. EPA Special Agents are federal law enforcement officers with the full authority to conduct investigations, carry firearms, make arrests for any federal crime and execute search and arrest warrants.

OCEFT works closely with the Department of Justice (DOJ) and state agencies that prosecute environmental crimes; federal, state and tribal law enforcement agencies; and with other EPA programs. OCEFT works primarily with DOJ's Environmental Crimes Section and the United States Attorneys to build strong cases for prosecution and occasionally works with state and tribal prosecutors. During investigations, OCEFT frequently combines its expertise with that of other law enforcement groups (such as the Department of Interior's Fish and Wildlife Service or the Department of Agriculture's Forest Service) to investigate cases with possible violations of a wide variety of laws. Criminal enforcement also relies on scientists, regulators, permit writers and other experts working in sister EPA offices such as the air, water and hazardous waste programs and civil enforcement.

During the execution of a criminal search warrant, support for forensic evidence collection such as sampling, monitoring and site documentation is provided by National Enforcement Investigations Center (NEIC) personnel, with additional support provided by Field Operations Program (FOP) personnel. EPA technical personnel, such as engineers and field inspectors, have received special training to assist the criminal investigative staff when needed. NEIC's specialized laboratories employ scientists, engineers, analysts, technicians and environmental and computer specialists to perform the essential science for environmental investigations. In addition to its accredited field support, the NEIC also provides forensic analytical support with its accredited laboratory. The NEIC Field Branch provides sampling and evidence collection support to CID. This support is provided both by the Lakewood staff and six outplaced technical staff stationed in six of the ten CID offices across the country. The Field Branch also provides multi-disciplinary teams that conduct investigations in support of civil case development. The investigations include multi-media and single-media inspections led by NEIC regulatory and technical experts who work closely with regional and state enforcement partners to identify potential compliance deficiencies.

CID's National Computer Forensics Laboratory (NCFL) has Special Agents trained to seize and analyze digital evidence, such as that found on computers, "PDAs" and cell phones. NEIC and NCFL all play critical roles, as do a number of other forensic, investigative, legal and prosecutorial partners, in successfully making cases.

Attorneys specializing in environmental crimes prosecutions advise on environmental regulations, enforcement-related legislation and other complex legal issues that arise during day-to-day operations of a national law enforcement program. The Legal Counsel Division's attorneys are experienced in both criminal and environmental law (as well as the civil enforcement program) and work with the investigators and DOJ in the investigation and prosecution of criminal cases. They provide legal guidance and training in criminal enforcement matters. A FIFRA inspector should not hesitate to contact any Special Agent or criminal enforcement counsel to ask questions or discuss any aspect (general or specific) of the criminal enforcement program. However, please note that the criminal enforcement program generally cannot discuss grand jury materials or privileged information with its civil enforcement counterparts.

RECOGNIZING POTENTIAL CRIMINAL VIOLATIONS

FIFRA inspectors should not attempt an in-depth investigatory analysis of whether criminal conduct has occurred or is occurring at regulated sources. Special Agents are specifically trained to collect evidence necessary to support any criminal charges.

FIFRA inspectors should refer to the Criminal Investigation Division (CID) any conduct or action that may potentially constitute criminal violations, such as:

- **Knowing or willful behavior**—defined as criminal under all federal statutes, or

- **Fraudulent reporting**—defined under all statutes and the United States code as criminal behavior.

The primary factor distinguishing a criminal case from a civil case is the **INTENT of the VIOLATOR**. Environmental crimes are committed either knowingly or willfully which means that the violator intends to commit an unlawful act, or engage in the prohibited conduct (i.e., not by accident or mistake) and should know or has full knowledge that the act is prohibited by law or regulation. Although environmental crimes usually are not committed with the specific goal of harming other people or the environment, they generally involve putting personal financial gain over public health and safety. In other words, most environmental crimes involve lying, cheating and stealing based upon a strong financial incentive.

Evidence of criminal wrongdoing may be blatant or subtle. The FIFRA inspector must try to learn as much as possible when one of the scenarios listed below is detected. The following should be brought to the attention of CID:

- **Conflicting data**— When two sets of books or inconsistent pesticide production, sale or distribution reports exist for the same product and/or facility.
- **Conflicting stories**—When an inspector is told one thing and learns something quite different through a record review, personal observation, or interview with a different person.
- **Unsubstantiated data**—When record keeping and reporting information cannot be verified or substantiated.
- **Deliberate actions**—When an employee says he/she was told or ordered to do something by his/her supervisor(s) that the FIFRA inspector knows to be illegal.
- **Claims of ignorance about requirements**—When those interviewed deny any knowledge of FIFRA requirements, yet documentation displaying knowledge is discovered in records, statements or interviews.

FIFRA inspectors are in a unique position to identify possible criminal activities such as falsified information in records and reports and illegal pesticide use. Facility staff employees may also volunteer information to inspectors about possible criminal activities. If any of these or other problems raise the inspector's suspicions, he/she must attempt to obtain further information through interviews, observations and records reviews and promptly refer findings to CID.

SEARCHES

Criminal Investigators/Special Agents may search a person or the person's property when seeking evidence of alleged criminal activity only under the following circumstances: (1) with the person's consent; or (2) after obtaining a warrant based upon sworn testimony that demonstrates the existence of "probable cause" to believe that a crime has been committed and

that the search is necessary to obtain evidence of the crime. The probable cause standard for obtaining a warrant in a criminal investigation is far more stringent than for a warrant in a civil enforcement case.

EPA's Special Agents seek and execute criminal warrants, but FIFRA inspectors may be requested to accompany criminal investigators to aid in the investigation. In such cases, FIFRA inspectors must follow the instructions of the criminal investigator since any evidence collected outside the authority of the search warrant would be considered to be illegally obtained and generally inadmissible at trial.

It is important to point out, however, that evidence of a crime discovered through civil enforcement activity is generally admissible in court to prove the crime. For example, information collected by a FIFRA inspector during a routine inspection (with consent or in an administrative warrant) could be admitted as evidence in a criminal case provided it was lawfully obtained during his or her normal course of duties. Similarly, evidence of a crime obtained in accordance with the open fields doctrine (e.g., an observation of illegal pesticide use from a public road) may be admissible.

Inspectors frequently ask how the reading of Miranda rights applies to the facility staff they interview, particularly if the interviewee's answer to questions begins to suggest that there may be criminal activity. Miranda rights only apply when a person is placed in custody, that is, once he or she has been arrested or otherwise deprived of freedom of action in any significant way by a law enforcement officer. Information provided in routine interviews is lawfully obtained evidence that may be used in furtherance of a criminal investigation and prosecution.

COMPELLING THE PRODUCTION OF INFORMATION

In addition to obtaining evidence through a search warrant, a prosecutor may subpoena witnesses to provide information through testimony to a grand jury. Although someone may be subpoenaed to require him/her to provide information in a civil proceeding, the prosecutor's ability to compel information in a criminal investigation is more powerful:

- A witness who fails to appear in response to a subpoena is subject to immediate arrest.
- An uncooperative witness can be forced to provide information through an enforceable court order.

For long-established and compelling policy reasons, testimony provided to a grand jury is secret and severe penalties are imposed on anyone who violates that secrecy. These secrecy rules may severely limit what can be disclosed by an agent concerning an investigation to persons not on the grand jury list of approved individuals. However, other non-grand jury information may be shared with the civil enforcement program.

Persons subpoenaed for a civil proceeding are obligated as follows:

- If a witness fails to comply with a subpoena, penalties can only be obtained after a hearing (a process that can take weeks).
- In addition, the information provided by the witness cannot be kept confidential if it falls within the scope of the other side's discovery requests.

DISCOVERY

Defense counsel may attempt to learn information about the government's case by directly contacting an EPA inspector. While an inspector is not prohibited from communicating with defense counsel, the inspector is in no way required to talk to defense counsel and should not do so without first consulting with an EPA attorney and having counsel present during the conversation.

INITIATING CRIMINAL INVESTIGATIONS

Criminal leads arise from a variety of sources, including tips from EPA regions, states and tribes, calls from disgruntled workers, anonymous tips and information from other law enforcement organizations. Leads are evaluated by the Special Agent in Charge (SAC) and an assigned agent, with a determination made within 45 days as to whether the lead should be opened as an investigation or referred elsewhere (e.g., civil enforcement at EPA, the state regulatory authority, or another federal agency). The factors involved in determining whether to open an investigation include whether the alleged violation resulted in real or potential harm, what type of conduct was involved, and various legal, technical and regulatory considerations. The initial assessment of a lead may also involve legal personnel—the Regional Criminal Enforcement Counsel (RCEC)—and technical personnel—NEIC Technical Coordinator (NTC)—working closely with the case agent. Both RCECs and NTCs are commonly co-located in the SAC offices.

If the reliability of the lead is unclear, the Special Agent will conduct a preliminary inquiry to determine the credibility of the allegation and make an initial assessment for the need of a more thorough investigation. This initial inquiry is brief and involves no extensive commitment of resources or time. The purpose is to reach an initial determination of the need for a complete investigation. The agent may consult with program enforcement personnel and legal staff to help determine whether a particular violation warrants criminal enforcement action.

CONDUCTING A CRIMINAL INVESTIGATION

If a decision is made to pursue a criminal investigation, the Special Agent contacts the regional legal program and other appropriate offices to determine whether any civil enforcement action is pending or contemplated against the investigative target. If technical support for the investigation is needed, CID requests that the appropriate regional program Division Director(s)

designate specific individuals to work on the investigation. All these activities are carried out in consultation with the Office of Criminal Enforcement, Forensics and Training.

CID uses investigative techniques similar to those employed by its law enforcement counterparts. After the receipt of lead information, state and federal environmental records and databases may be reviewed to determine a suspect company's regulatory history or an individual's criminal history. In all cases, interviews are conducted to gain a detailed view of the facts, and that often leads to more detailed investigative steps, such as surveillance of a facility or suspected individuals, issuance of grand jury subpoenas (through the Department of Justice), execution of search warrants where probable cause of criminal violations exists and the use of traditional covert and technical investigative techniques. Special agents review documents and data from environmental, inspection and other databases and files and determine what additional expertise is needed to prove the crime in court. The Special Agent manages the investigation, under the supervision of the SAC, and is responsible for the following:

- Determining the basic investigative approach.
- Conducting interviews.
- Assembling and reviewing records.
- Planning and performing surveillance.
- Coordinating with the U.S. Attorney's office and other federal, state and local law enforcement agencies.
- Communicating with informants.
- Contacting other witnesses.
- Performing other investigative functions.
- Completing all required reports.
- Carrying out all coordination and notification requirements.

Inspectors may be assigned to assist the Special Agent in one or more of these above duties as requested by CID.

SECURITY OF CRIMINAL INVESTIGATIONS

FIFRA inspectors who have knowledge of criminal investigations should not disclose the information or discuss any criminal investigations with anyone outside of the Agency.

Agency policy is to neither confirm nor deny the existence of a criminal investigation. If a FIFRA inspector receives a written or verbal request for information from a third party (e.g., the news media), it must be immediately referred to the CID Special Agent who will determine the

response in consultation with other Agency offices. In general, the Department of Justice (DOJ) responds to such inquiries.

If a FIFRA inspector possesses written materials pertaining to a criminal investigation, he/she must treat these materials with special care and attention and ensure that they are stored in secure office space, in locked filing cabinets and/or evidence vaults.

PARALLEL CRIMINAL AND CIVIL PROCEEDINGS

FIFRA includes both civil and criminal enforcement authorities and EPA may use both authorities to identify and resolve FIFRA violations. FIFRA inspectors should note that the Agency may pursue criminal and civil enforcement actions on separate but "parallel" tracks. Even if the parallel criminal and civil enforcement actions relate to the same violation, EPA maintains a clear distinction between the two proceedings. FIFRA inspectors must follow these guidelines when involved in ongoing parallel proceedings:

1. Until the Agency refers a matter to the DOJ for possible criminal prosecution, all FIFRA inspectors who are EPA employees may continue to collect information/data from potential defendants with the understanding that it may be used in either a civil or a criminal enforcement action. However, once the Agency has referred a matter to the Department of Justice for possible criminal prosecution, all FIFRA inspectors and other EPA employees should not continue to collect information/data from potential criminal defendants, unless they are acting as an investigator for the prosecutor's office or CID and have clear authority to obtain such information/data for an existing regulatory purpose that is wholly separate and independent of the criminal investigation.
2. EPA reserves the right to take criminal or civil enforcement action based on information obtained by FIFRA inspectors. Therefore, FIFRA inspectors (whether EPA employees or not) shall never tell a person or entity that EPA will not use the information obtained during an inspection as evidence in a criminal or civil case.
3. Direct any questions concerning parallel proceedings to the criminal or civil enforcement counsel at EPA.

COMPLIANCE WITH THE JENCKS ACT

The purpose of the federal Jencks Act (18 U.S.C. §3500) is to allow the defendant in a criminal prosecution to have, for impeachment purposes, all of the relevant and competent statements of a governmental witness. If the defense's ability to cross-examine a witness is impeded because the government lost, either deliberately or inadvertently, the Jencks Act material, the Court may decide either not to allow the witness to testify or to strike the witness's entire testimony. Needless to say, the effect of excluding a government witness's testimony could be

significant. Courts expect law enforcement agencies, including EPA, to have procedures to preserve potential Jencks Act material.

Essentially, the Jencks Act provides that the relevant notes, records and reports of a witness who has testified for the government in a criminal prosecution must be turned over to the defense if the defense requests them through the court. The request can only be made after direct examination of the witness, and material that does not relate to the subject matter of the testimony is exempt from disclosure. The effect is limited, after-the-fact discovery. (In civil cases, discovery processes give the other side almost unlimited access to government information on the case prior to trial.)

For the inspector, the principle effect of the Jencks Act is to underscore one of the major points of this Manual—that accurate and complete notes, records and reports are not only good practice, but essential for ensuring a successful enforcement action whether administrative, civil or criminal. Further, notes and records must be factual and contain no opinions or biases of the inspector. Finally, to avoid any potential appearance that Jencks Act material has been lost or intentionally destroyed, the inspector must not throw anything away, not even a scrap of paper with rough calculations on it, without first consulting with the criminal investigation team. All materials associated with a criminal investigation must be stored in accordance with security procedures.

PARTICIPATION IN GRAND JURY INVESTIGATIONS

If a FIFRA inspector that is an EPA employee is called upon to assist in a grand jury investigation under DOJ's supervision, he/she must follow the "Agency Guidelines for Participation in Grand Jury Investigations." Copies of these guidelines are available from the RCECs and OECA.

An official website of the United States government

Pesticide Registration Manual: Introduction

In this chapter:

- Introduction
- Why register pesticides with EPA
- The label is the law!
- How to use This manual

Introduction

This manual is intended as a resource for companies and individuals who wish to have their pesticide products registered by the U.S. Environmental Protection Agency (EPA). EPA's pesticide review and oversight is conducted by the Office of Pesticide Programs (OPP) <https://epa.gov/pesticide-contacts> within the Office of Chemical Safety and Pollution Prevention. OPP comprises nine divisions of scientists, regulatory specialists, and other staff. This manual includes information on many types of registration actions; however, it utilizes the procedures for registering a "new" pesticide product in most of its examples.

Why Register Pesticides with EPA

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates all pesticides that are sold and distributed in the United States. The term "pesticides <https://epa.gov/ingredients-used-pesticide-products/basic-information-about-pesticide-ingredients>" includes pesticides, herbicides, rodenticides, antimicrobial products, biopesticides, and other substances used to control a wide variety of pests. A pesticide product is defined as a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold and includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide. (40 CFR 152.3).

Before any pesticide product that EPA has not exempted from registration requirements can be lawfully sold or distributed, EPA performs a rigorous, comprehensive scientific assessment of the product, resulting in a registration decision. Under this review, the Agency evaluates

- the product's active ingredient(s) <https://epa.gov/pesticide-registration/registration-information-type-pesticide>,
- other constituent substances (including inert ingredients <https://epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance>), and
- the proposed use pattern(s)

to ensure that, when the product is used according to labeled directions, no unreasonable adverse effects on human health or the environment will occur.

When EPA has determined that no unreasonable adverse effects to human health or the environment will result from the sale or distribution of a pesticide product, it grants the applicant a license or "registration" to legally sell and distribute the product in the United States. Once an EPA registration has been granted, applicants will then need to comply with the individual registration requirements imposed by the States in which they wish to market their product. Refer to Chapter 17 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority> for information on State regulatory authorities. The establishment in which a pesticide product is produced must also be registered. Refer to Chapter 14 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or> for information on pesticide producing establishments.

The Label is the Law!

Once EPA has granted a registration, EPA not only notifies the requesting company of the decision but also will approve a submitted label for the product. All registered products must include an approved label on every package. The pesticide product's label is a legal document. The label is the law! Once EPA approves a label during the registration evaluation, it generally may not be altered or changed by the company unless specifically authorized by EPA during a subsequent label review.

A pesticide product's label is of utmost importance as the label is the primary mechanism to inform the end-user about how to use and apply the product to achieve the product's useful functions, as well as which precautions must be followed to protect both human health and the environment. Thus, as part of any registration application submitted to EPA, applicants must provide a proposed label containing detailed information. During its review, EPA can approve the label as submitted, approve the label with comments, or disapprove the submitted label.

For more information on labels, see Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product> in this manual. More detailed information on labels can be found in EPA's Label Review Manual <https://epa.gov/pesticide-registration/label-review-manual>.

How to Use This Manual

Companies and individuals seeking to obtain pesticide registrations are referred to as pesticide "applicants" throughout this manual. After applicants have a pesticide registered, they are referred to as "registrants."

Registered pesticides generally can be divided into two categories: manufacturing-use products that are used to formulate other pesticide products and end-use products that are distributed or sold to the user for controlling pests or defoliating, desiccating, or regulating the growth of plants. While both the manufacturing-use and end-use products must be registered, the focus of this manual is applications for the registration of end-use products. Applicants should contact a registration ombudsman <https://epa.gov/pesticide-contacts/contacting-epa-about-regulating-pesticides-issues> for questions concerning the registration of manufacturing-use products that aren't addressed in this manual.

This manual is organized into 21 chapters (see Table of Contents at right) that comprehensively discuss issues related to the registration of pesticide products. Each chapter includes a list of references that can be used to further understand the issues presented.

In addition to describing EPA's registration process, this manual also provides detailed information about the responsibilities of applicants/registrants - before, during, and after the review process.

The manual begins with a high-level overview of the entire pesticide registration process <https://epa.gov/node/186165> aimed at those who have not previously registered a pesticide product. It summarizes the information in the other chapters of the manual.

In Chapter 1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide> there are discussions of the legal and statutory framework of EPA's oversight of pesticides in the United States and what types of products are required to undergo an EPA evaluation. Chapter 1 also provides an overview of how to have a pesticide evaluated by EPA - the types of data required, how it is submitted, and other supporting documentation.

Chapters 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>, 3 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>, and 4 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations> provide specific information to help applicants determine data and other registration requirements depending on whether their product is classified as an antimicrobial, biopesticide, or conventional chemical pesticide.

Chapter 5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees> discusses changes that were made to EPA's pesticide review program following enactment of the Pesticide Registration Improvement Act of 2003 (PRIA), which was subsequently reauthorized by the Pesticide Registration Improvement Renewal Act of 2007 (PRIA 2) and the Pesticide Registration Improvement Extension Act of 2012 (PRIA 3) <https://www.govinfo.gov/content/pkg/uscode-2012-title7/html/uscode-2012-title7-chap6-subchapii-sec136w-8.htm>. PRIA established pesticide registration fees for some registration actions, requiring applicants to pay a fee, in exchange for which, EPA is obligated to reach registration decisions within defined timeframes.

Chapters 6 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide> and 7 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation> discuss amendments to currently registered pesticides and instances that do not require EPA review but that can be accomplished by notification to EPA.

Chapter 8 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients> explains how EPA considers inert ingredients in the evaluation of pesticide products and what type of documentation is required for review. Inert ingredients are pesticide product ingredients that are not active against target pests.

Chapter 9 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered> explains what requirements must be adhered to when companies that are not the original registrant distribute a registered pesticide product.

Chapter 10 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements> addresses data compensation issues that arise if an applicant chooses to cite a different company's proprietary data for EPA's review.

Chapter 11 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions> discusses tolerance petitions, i.e., which data are required and how EPA evaluates food uses of pesticides to determine whether a maximum residue level of the chemical can remain on food without causing harm to people, including sensitive populations such as infants and children.

Chapter 12 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit> discusses data requirements and EPA review procedures for "Experimental Use Permits" (EUPs). An EUP is a permit authorized under FIFRA section 5 that allows applicants to conduct testing of a new proposed pesticide or new proposed use.

In Chapter 13 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>, "Devices" are discussed in detail. In general, if a pest is controlled by a physical or mechanical action, the product may be considered a "device" and may not require registration by EPA. Devices are subject to other types of regulatory oversight, as listed in 40 CFR 152.500.

Chapters 14 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>, 15 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>, and 16 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and> provide specific information on obtaining an EPA Establishment Number, how to submit data and Confidential Business Information to EPA, and how to transfer product registrations and data rights to different companies.

Chapters 17 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority> and 18 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency> present useful information on the role played by state regulatory agencies and other federal agencies in pesticide oversight in the United States. Registrants may also have certain obligations under state and other federal agencies.

Chapters 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> and 20 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them> provide detail on obtaining publications and forms related to pesticides.

Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> gives specific directions for submitting applications to EPA, and how to contact appropriate offices within the Office of Pesticide Programs.

For More Information

Code of Federal Regulations citations are available in the e-CFR.

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>
2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>
19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON FEBRUARY 6, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

How to Register a Pesticide – A Guide for Applicants New to the Process

Guidance Document: Registration Manual

How to Register a Pesticide Product – A Guide for Applicants New to the Process

Issued By: Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, United States Environmental Protection Agency

Date of Issuance: January 15, 2021

This guidance document is an addition to the Pesticide Registration Manual originally issued on April 20, 2017

Unique ID: EPA 705-G-2021-3726

Related Authority: 7 U.S.C. 136 *et seq.*

Summary: This document is an introductory resource for companies and individuals who wish to sell their pesticide products in the United States.

Non-Binding Disclaimer: This guidance was prepared pursuant to Executive Order 13891 and "EPA Guidance; Administrative Procedures for Issuance and Public Petitions" (85 FR 66230, October 19, 2020). The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

On this page:

- Overview
- Learn about the pesticide product registration process
- Determine what type of product you have

- Determine what data you need to support your product
- Determine the registration fee and review timeframe for your product
- Consider using a consultant
- Talk to EPA about your plans once you have read the guidance
- Obtain an EPA company number
- Complete the application package
- Submit the application package and pay the fee
- Respond to any issues raised during EPA's review process
- EPA makes regulatory determination
- Apply for state registration
- Additional requirements for pesticide producers and applicants

---

Overview

Welcome to the pesticide product registration process. This page is an introductory resource for companies and individuals who wish to sell their pesticide products in the United States. While this provides a high-level summary of the registration process, applicants are responsible for fully understanding the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) <https://epa.gov/node/39777> and its regulations.

Under FIFRA, EPA regulates all pesticides that are sold or distributed in the United States. A pesticide is:

- A substance intended to prevent, destroy, repel or mitigate pests;
- A substance intended for use as a plant regulator, defoliant or desiccant; or
- Any nitrogen stabilizer <https://epa.gov/node/127393>.

The three major pesticide types are:

- **Conventional pesticides** such as insecticides, herbicides, fungicides and rodenticides;
- **Antimicrobial pesticides** such as sterilants, sporicides, disinfectants, sanitizers, germicides, and products that control growth of microorganisms of economic and aesthetic significance; and
- **Biopesticides** such as biochemicals, microbe-containing (microbial) pesticides and plant-incorporated protectants (PIPs).

Most end-use pesticide products also contain inert (other) ingredients, or substances in addition to the active ingredient(s). Manufacturing-use products, on the other hand, are intended and labeled for formulation and repackaging into end-use pesticide products. They often do not contain intentionally added inert ingredients but may contain impurities that need to be specified. See Chapter 2 <https://epa.gov/node/32677> of this Registration Manual for more information.

Before a pesticide product can be lawfully sold or distributed, EPA performs a comprehensive scientific assessment of the product, resulting in a regulatory decision (i.e., whether or not to approve the product for sale and/or distribution in the United States). In accordance with FIFRA, registered pesticides cannot cause unreasonable risks to humans or the environment.

There are some pesticides EPA has exempted from the federal requirement for registration. To determine whether your product is exempt, please review 40 CFR 152.25 and this page about minimum risk pesticides <https://epa.gov/node/64449>. The linked pages provide information that should permit you to determine if your product meets the criteria for the exemption. If you determine the product does not meet the criteria, registration would be required.

Before you contact EPA with questions about the registration process, please read this webpage and review the materials it references. These resources will answer some of your questions and help you ask questions specific to your situation.

Learn about the pesticide product registration process.

First, read the Introduction and the first two chapters of this Pesticide Registration Manual <https://epa.gov/node/17603>, which is a valuable resource that provides all the information you need on this process. We also recommended you refer to the Label Review Manual <https://epa.gov/node/29541> for drafting the product label for your pesticide.

Determine what type of product you have.

Each pesticide type has a different process for registration:

- Conventional Pesticides <https://epa.gov/node/17605>
- Biopesticides <https://epa.gov/node/17619>
- Antimicrobial Pesticides <https://epa.gov/node/17607>

Determine what data you need to support your product.

In evaluating a pesticide registration application, EPA assesses a wide variety of studies to determine the likelihood of adverse effects (i.e., risk) to human health and the environment from exposures associated with use of the product.

Applicants must generate scientific data to address concerns about the identity, composition, potential adverse effects and environmental fate of each pesticide. These data allow us to evaluate whether a pesticide might affect a range of non-target organisms, including humans, plants, animals, and endangered or threatened species. Learn about data requirements <https://epa.gov/node/19057>

You may also discuss and confirm the data and labeling requirements with EPA before submitting your application. Answering the following questions may help you better determine your data needs:

- Will you provide data, cite data, or use other methods (e.g., data waiver or bridging, supported by scientific rationale) to support the proposed product?
    - All products must be supported by data (e.g., product chemistry, acute and chronic toxicity, environmental fate and ecological effects, etc.) for the proposed use pattern. Learn more about:
    - Health Effects Test Guidelines <https://epa.gov/node/85855>
    - Product Properties Test Guidelines <https://epa.gov/node/85833>
    - Ecological Effects Test Guidelines <https://epa.gov/node/85847>
    - Residue Chemistry Test Guidelines <https://epa.gov/node/85853>
    - Microbial Pesticide Test Guidelines <https://epa.gov/node/85867>
    - Biochemicals Test Guidelines <https://epa.gov/node/85863>
    - Data Requirements for Registration of Antimicrobial Pesticides <https://epa.gov/node/82271>
    - If your proposed product is substantially similar <https://epa.gov/node/32677> to another EPA-registered product, you may be able to rely on existing studies.
    - You must choose whether to conduct studies and submit the data, cite studies already evaluated by EPA, or use other methods available to fulfill data requirements.
    - If you are citing another company's data, you must first determine whether you need to pay or get authorization from the data's owner to use it.
- Learn about data compensation requirements. <https://epa.gov/node/34345>
- View a list of companies that have submitted data to EPA <https://epa.gov/node/86423>.
- If you do not own the source of the active ingredient (the technical source), the technical source is registered (has an EPA registration number), and you are relying on the citation of that product to fulfill the data requirements for the active ingredient (generic data), you can use the Formulator's Exemption form (Form 8570-27 <https://epa.gov/sites/production/files/2013-08/documents/8570-27.pdf>) to address the generic data requirements specific to the active ingredient.
- If the technical source is not EPA registered, or the use patterns on your proposed label are not supported by a technical source that is EPA registered, you will be responsible for addressing all generic data requirements <https://epa.gov/node/19057> by submitting studies, citing existing data from registered sources or using other methods (e.g., providing scientific rationale).
- Will you be making claims about your product's effectiveness against public health pests <https://epa.gov/node/57607>?
- Efficacy (product performance) data are required if your product will be making claims against public health pests, pests that affect building structure (e.g., termites), or certain invasive pests.
- Learn about product performance test guidelines <https://epa.gov/node/85829>
- Learn about efficacy testing for pesticides targeting certain invertebrate pests <https://epa.gov/node/140837>
- The Agency generally does not require submission of efficacy data to support non-public health-related claims (e.g., control of odor-causing bacteria, weeds, plant pathogens). However, the applicant is still responsible for ensuring that these products perform as intended by developing and keeping efficacy data on file. EPA retains the right to require submission of efficacy data for non-public health related claims on a case-by-case basis.

AR0000351

- Will your pesticide be used on food or feed crops or in a food processing or storage area? If so, a tolerance or an exemption from the requirement of a tolerance <https://epa.gov/node/72001> must be established for each active and inert ingredient in the formulation before the pesticide can be registered. See Chapter 5 of this Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees#fees> for more information on costs and timeframes.

Determine the registration fee and review timeframe for your product.

The Pesticide Registration Improvement Act (PRIA) <https://epa.gov/node/44857> requires that EPA charge registration fees and assign a review timeframe for each registration application. These fees and timeframes vary depending on the type of activity being requested.

- Before submitting the application, see the fee determination decision tree <https://epa.gov/node/45435> to identify the PRIA category of your application, EPA's interpretation of the category of your application, the required fee, and the review timeframe.
    - Fees may be reduced under some circumstances <https://epa.gov/node/49547>. There are provisions for waiving up to 75 percent of the fee if you qualify as a small business. The fee waiver application must be submitted with the registration application. Learn more about fee waivers for small businesses <https://epa.gov/node/46523>.
- In some circumstances, applications may be exempt from registration fees.
    - Learn more about Inter-Regional Project Number 4 (IR-4) exemptions <https://epa.gov/node/46547>
    - Learn more about exemptions for federal and state governments <https://epa.gov/node/46567>
- Learn more about fees. <https://epa.gov/node/158729>

Consider using a consultant.

If you have not previously registered a pesticide product, it may be helpful to obtain the services of a regulatory consultant. An experienced consultant can help you navigate the registration process, which will save time and resources. To identify a consultant, consider doing a web search on "pesticide regulatory consultant" or contacting a trade group for assistance.

EPA does not endorse or make any recommendations for any consultant. We strongly recommend you interview several consultants and check at least three recent references before selecting one.

Applicants located outside of the United States **must** have an agent residing in the United States to act on their behalf in all registration matters. This agent may or may not be a regulatory consultant.

The appropriate way to designate a consultant or agent is explained in Chapter 14 of this Pesticide Registration Manual <https://epa.gov/node/39329>.

Talk to EPA about your plans once you have read the guidance.

It is EPA's hope that the material in this preface and the rest of the Pesticide Registration Manual provides applicants with all of the information they need to submit a registration application.

If, however, you have additional questions that are not covered in these materials, EPA staff may be available to address your questions via email, phone calls or an in-person meeting. These opportunities provide avenues to discuss and confirm data needs, pesticidal claims, and labeling requirements that apply to your application. It is helpful if you provide as many details as possible about your proposed application in an introductory email to the appropriate EPA registration contact for your product.

- Contact the appropriate division based on your pesticide type <https://epa.gov/node/16875>.
- Learn more about pre-application meetings for antimicrobial pesticide applications <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration#meeting>.

Obtain an EPA company number.

An EPA company number is a unique identifier assigned to a company that wishes to register a pesticide with EPA. These companies are commonly called registrants.

Registrants must obtain a company number prior to registering their first product with the Agency. To obtain the company number <https://epa.gov/pesticide-registration/pesticide-registration-manual-how-obtain-company-number-and-register-official#:~:text=how%20to%20request%20a%20company,correspondence%20to%20the%20official%20address.>, send a signed letter on company letterhead to request a company number and establish an official address with EPA.

Complete the application package.

Make sure you have all required contents of the application package <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product#required>.

Submit the application package and pay the fee.

For more information on submitting the package, review the following chapters of the Registration Manual:

- Chapter 15 (Submitting Data and Confidential Business Information) <https://epa.gov/node/34457>
- Chapter 20 (Forms and How to Obtain Them) <https://epa.gov/node/34535>
- Chapter 21 (Directions for Submitting Applications and Contacting EPA) <https://epa.gov/node/34537>

Learn more about paying PRIA application fees <https://epa.gov/node/46913>.

Respond to any issues raised during EPA's review process.

When EPA receives the application and applicable PRIA fee, the Agency has 21 days, known as the 21-day Content Screen <https://epa.gov/node/46899>, to determine if the application has all required components. EPA will determine whether it contains all:

- Forms;
- Composition;
- Labeling;
- Data formatted as described in the Agency's guidance (PR Notice 11-3 <https://epa.gov/node/51183>); and

- Documentation of fee payment, including any requests for a fee reduction or waiver or exemption.

Any deficiencies identified during the 21-day Content Screen that are not corrected by the applicant during the screening process may lead to EPA's rejection of the application and retention of 25 percent of the fee.

Some examples of issues found during this part of the review process:

- Missing or unsigned forms.
- Missing data or scientific rationale in lieu of data, or unacceptable scientific rationale or bridging argument.
- Inert ingredients <https://epa.gov/node/17833> not approved by EPA.

Following the 21-day Content Screen, EPA checks to make sure the application is ready for comprehensive review, which is called the 45/90-day Preliminary Technical Screen. In conducting this screening, EPA determines whether the data and information submitted with the application are:

- Adequate and sufficient;
- Consistent with the proposed labeling and any proposed tolerance or tolerance exemption; and
- Sufficient such that a full review could result in the granting of the application.

If the application fails the technical screening and cannot correct the deficiencies within 10 business days after receipt of EPA's notification of the failure, EPA will reject the application and retain part of the application fee based on the Fee Reduction Tables <https://epa.gov/pria-fees/overview-pria-fee-reduction-and-refund-formula>.

Applicants can use the Checklists for 45/90 Preliminary Technical Screen <https://epa.gov/node/47055> to help ensure their applications are complete and may submit completed checklists with their applications.

Once your application passes both the 21-day Content Screen and 45/90-day Preliminary Technical Screen, EPA will complete a comprehensive science review. Any data deficiencies or additional information needed to complete the reviews will result in EPA notifying the applicant of the issues. The applicant will have 75 days to make corrections or additions to complete the application.

If the applicant believes that the deficiencies cannot be corrected within 75 days, the applicant can propose a new date by which the application will be complete. If, after 75 days, the applicant has not responded, or if the applicant subsequently fails to complete the application within the time scheduled for completion, EPA will terminate any action on the application and will treat the application as if it had been withdrawn by the applicant. Any refunds provided will be calculated using the Fee Reduction Tables <https://epa.gov/pria-fees/overview-pria-fee-reduction-and-refund-formula>.

EPA makes regulatory determination.

EPA will make a regulatory decision using risk assessments based on review of the submitted data, information and proposed label.

If EPA grants the registration, the registration may be either unconditional or conditional <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide#unconditional>.

Apply for state registration.

If your application is approved by EPA, you must then apply for registration in the states where you plan to sell your product.

- Find contact information for state pesticide regulatory agencies <http://npic.orst.edu/reg/state_agencies.html>.

Additional requirements for pesticide producers and applicants.

If you are producing or formulating a pesticide, you must comply with FIFRA Section 7, Registration of Establishments.

- Obtain an establishment number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or> for each place or facility where you will manufacture the product.
- Note that annual reports are required for establishments <https://epa.gov/compliance/pesticide-establishment-registration-and-reporting>, even if there is no production.

Once your product is registered, you also must pay annual registration maintenance fees <https://epa.gov/pesticide-registration/annual-pesticide-registration-maintenance-fees>.

This has been a general overview of the pesticide product registration process. The resources on this page have extensive information, but you may contact us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> if you still have questions.

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON MARCH 2, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 1 - Overview of Requirements for Pesticide Registration and Registrant Obligations

In this chapter:

- Introduction
- Laws and Regulations Pertaining to Pesticide Registration
- Identifying Which Products Require Registration
  - Substances vs. Devices
  - Definition of Intent
  - Toxicity to Humans and Nontarget Organisms
- Products or Substances that Are Regulated but Not Registered as Pesticides
  - Adjuvants
  - Devices
  - Pesticide Intermediates
  - Pesticides and Pest Control Organisms Exempt from Registration Requirements
- Pesticides Intended for Use on Food or Feed
- Import and Export of Pesticides
- Types of Pesticide Registration
  - Obtaining a Registration for a Pesticide Product
  - Obtaining a Supplemental Registration to Distribute a Product Registered by Someone Else
  - Amending the Registration of a Product Already Registered with EPA
  - Unconditional/Conditional Registration
- Registrant Obligations
- State Pesticide Regulatory Agencies
- Enforcement and Compliance

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. **Requirements for Pesticide Registration and Registrant Obligations**
2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>

- Contacts for Additional Information
- References Cited in Chapter 1

Introduction

This chapter provides an overview of the federal laws that govern EPA's oversight of pesticide use in the United States. The chapter also introduces concepts further elaborated in later chapters of this manual, such as which products are subject to EPA's review, how EPA evaluates a pesticide chemical's toxicity to humans or other organisms, how EPA evaluates a chemical's environmental risk, how EPA evaluates pesticides intended for use on food crops and nonfood sites, different types of EPA responses, role of state regulations, and obligations of companies and individuals seeking a pesticide registration (referred to as "applicants").

Laws and Regulations Pertaining to Pesticide Registration

The primary federal law that governs how EPA oversees pesticide use in the United States is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, originally enacted in 1947. This law has been significantly amended several times, notably in the recent past by the Food Quality Protection Act of 1996 (FQPA) <https://epa.gov/node/111505> and by the Pesticide Registration Improvement Act of 2003 (PRIA), which was reauthorized by the Pesticide Registration Improvement Extension Act of 2012 <https://epa.gov/pria-fees>.

3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

AR0000362

> - FQPA significantly strengthened the safety criteria in the Federal Food, Drug, and Cosmetic Act (FFDCA) <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>, under which EPA evaluates pesticide uses on food crops.
> - PRIA established pesticide registration fees <https://epa.gov/pria-fees> for some registration actions, under which applicants are required to pay a fee and, in exchange, EPA is obligated to perform certain registration functions within defined timeframes.

EPA also derives its authority to regulate pesticide residues on food items from provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA and FFDCA require EPA to carefully evaluate any pesticide intended for use on food or animal feed crops before making a registration decision. If EPA determines that use of the product would result in residues of the chemical(s) in or on food/feed items, the Agency may not register the product under FIFRA unless EPA can determine that the residues are "safe" under the FFDCA. The FFDCA defines "safe" to mean that there is "a reasonable certainty of no harm" from the exposure to the residue in food and from other non-occupational sources.

After making a determination as to safety, the Agency may establish a "tolerance <https://epa.gov/pesticide-tolerances/about-pesticide-tolerances>," i.e., a maximum permissible pesticide residue on a particular food/feed commodity. Alternatively, EPA may establish an exemption from the requirement of a tolerance, which would allow any amount of a pesticide residue to remain in or on food or feed, if EPA determines that granting the exemption would meet the FFDCA safety standard. There is a more detailed discussion of the FFDCA requirements and pesticide tolerances later in the "Pesticides Intended for Use on Food or Feed" section of this chapter.

Further legal and technical authority regarding how EPA regulates pesticides in the United States is found in FIFRA's implementing regulations at Title 40 of the Code of Federal Regulations (40 CFR) Parts 150-189. These sections of 40 CFR govern the sale, distribution and use of pesticides. Persons or companies subject to the law are responsible for understanding and complying with FIFRA, FFDCA, and the relevant sections of 40 CFR.

Identifying Which Products Require Registration

For a company to know if EPA must register its pesticide product(s), it is necessary to know what the law defines as a pesticide. Anyone who plans to sell or distribute a product in the United States that is intended to control a pest or regulate plant growth should become familiar with the definition of pesticide in the law and regulations.

The term pesticide, as defined in FIFRA section 2(u) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> means:

> 1. any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest;
> 2. any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; and
> 3. any nitrogen stabilizer.

AR0000363

EPA has listed in 40 CFR 152.6 substances that are excluded from regulation by FIFRA. Provided they meet the conditions or criteria specified in 40 CFR 152.6, such substances include liquid chemical sterilants, nitrogen stabilizers, human drugs, animal drugs, animal feeds vitamin hormone products, and products intended to aid the growth of desirable plants. Further, EPA has listed, in 40 CFR 152.8, fertilizer products that don't contain pesticide and products intended to force bees from hives for the collection of honey as products that are not pesticides because they are not for use against pests. When other products are not pesticides because they are not intended for a pesticidal purpose is explained in 40 CFR 152.10.

Substances vs. Devices

The use of the terms substance and mixtures of substances in the definition of pesticide provides the key to separating pesticides from devices (discussed below). If the product contains a substance that is intended to prevent, destroy, repel, or mitigate a pest or constitutes a plant regulator, defoliant, desiccant, or nitrogen stabilizer, then the product is considered to be a pesticide and, in general, will require registration (exceptions to registration also discussed below).

If the pest is controlled by physical or mechanical action (as opposed to a substance), then the product is considered a device and registration by EPA is not required. However, devices are subject to other provisions of the law, which are more thoroughly explained in Chapter 13. <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>

Definition of Intent

As set forth at 40 CFR section 152.15, a substance is considered to be intended for a pesticidal purpose, thus requiring EPA registration, if:

> - The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):
>
>   - that the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or
>   - that the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or
>   - the substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or
>   - the person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for pesticidal purpose.

Toxicity to Humans and Nontarget Organisms

Pesticides are substances that prevent, destroy, repel, or mitigate a pest. A product's relative toxicity to humans or other nontarget organisms does not make it a pesticide. However, the product's toxicity to humans and other organisms is carefully evaluated during EPA's registration evaluation process. When EPA determines that a pesticide

AR0000364

product can be registered for use, the Agency has concluded that the use of the pesticide product will not cause unreasonable adverse effects to humans or the environment when applied according to the label directions and restrictions.

It is important to become familiar with the other definitions in the law and regulations. The definitions for devices, active and inert ingredients, and pests are terms that will be vital for fully understanding the definition of a pesticide.

- **Active ingredient (A.I.)** – "Any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a), except as provided in [40 CFR] § 174.3." 40 CFR 152.3. See also FIFRA 2(a).
- **Inert ingredient** – "Any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product, except as provided by [40 CFR] § 174.3." 40 CFR 152.3. See also FIFRA 2(m).
- **Device** – Devices are described in a following section in this chapter, FIFRA section 2(h) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> and in detail in Chapter 13 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>.
- **Pests** – This term means "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the [Agency] declares to be a pest under [FIFRA section 25(c)(1) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>]" FIFRA 2(t).

Important Note: For assistance in determining whether a product is a pesticide or device under FIFRA, you may contact the Registration Division <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-registration-division>, the Antimicrobials Division <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-regulatory-divisions-ad-bppd-prd-rd>, or the Biopesticides and Pollution Prevention Division <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-biopesticides-and-pollution-prevention> Ombudsmen in the Office of Pesticide Programs (OPP). The contact should be made in writing and should include detailed information about the intended uses and composition of the product. Submission of a proposed label for the product would also be helpful. The addresses and/or FAX numbers for the Regulatory Division Ombudsmen are found in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>. **Please do not send any confidential information via FAX or e-mail**.

Products or Substances that Are Regulated but Not Registered as Pesticides

Adjuvants

For pesticide regulation, adjuvants are chemicals added to a pesticide by users to improve the pesticide's efficacy. Agricultural chemical adjuvants are grouped according to their intended purpose in a tank mix. Examples of adjuvants include:

- acidifying agents,
- buffering agents,
- anti-foam agents,
- defoaming agents,
- anti-transpirants,
- dyes and brighteners,
- compatibility agents,
- crop oil concentrates,
- oil surfactants,
- deposition agents,
- drift reduction agents,
- foam markers,
- feeding stimulants,
- herbicide safeners,
- spreaders, extenders,
- adhesive agents,
- suspension agents,
- gelling agents,
- synergists,
- wetting agents,
- emulsifiers,
- dispersing agents,
- penetrants,
- tank and equipment cleaners,
- neutralizers,
- water absorbents, and
- water softeners.

Such agents are often included in pesticide formulations as "other ingredients," in which case the ingredient is reviewed during registration and any necessary tolerances or exemptions from the requirement of a tolerance are established. Where a product label directs the user to add a particular adjuvant before use, the registering division will treat that adjuvant as if it were an "other ingredient" in making the registration decision, and will assure that any necessary tolerances or exemptions from the requirement of a tolerance are established. It also would be within the Agency's authority to treat any tank-mixed substance as part of the pesticide (and thus needing an FFDCA tolerance) in that it met the FIFRA definition of pesticide – i.e., a "mixture" of substances intended to kill a pest.

Devices

A device is defined in FIFRA section 2(h) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> as "any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than humans and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides) when sold separately." Tamper-resistant bait boxes for rodenticides are an example of application equipment that does not fall within the definition of a device.

Items that depend more upon the performance of a person than on the performance of the device itself (e.g., flyswatters) are considered devices but are not subject to regulation.

As already stated, registration is not required for devices although devices are subject to other provisions of the law. Please refer to Chapter 13 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices> for further information. A nontechnical fact sheet on devices <https://epa.gov/pesticides/pesticide-devices-guide-consumers> is also available.

Pesticide Intermediates

Pesticide "intermediates" are substances that may not themselves be pesticides, but are used in the synthesis of the active ingredient or the manufacture of the pesticide product. Examples of intermediates are the starting materials used to synthesize by chemical reactions or purify a technical grade of the active ingredient. A pesticide intermediate may be produced at the same site as the final pesticide product or obtained from other sources. Some pesticide intermediates are also pesticides because they are intended for a pesticidal purpose. See 40 CFR section 152.15 for examples of what EPA considers a substance intended for a pesticidal purpose. Pesticide intermediates that are not also pesticides are not subject to registration under FIFRA but are subject to regulation under the Toxic Substances Control Act (TSCA) <https://epa.gov/laws-regulations/summary-toxic-substances-control-act>. Questions regarding chemicals or compounds that are not pesticides should be referred to EPA's Office of Pollution Prevention and Toxics (OPPT). <https://epa.gov/chemicals-under-tsca>

Pesticides and Pest Control Organisms Exempt from Registration Requirements

The following pesticides, pest control organisms, and treated articles are exempt from the registration requirements of FIFRA under 40 CFR Part 152, Subpart B:

AR0000367

Exemptions for pesticides regulated by another Federal Agency (40 CFR 152.20)

- Certain biological control agents are exempt (except for eucaryotic microorganisms, including protozoa, algae, and fungi; procaryotic microorganisms, including bacteria; and viruses).
- All living plants intended for use as biological control agents are exempt from the requirements of FIFRA. However, plant-incorporated protectants are not exempt pursuant to this section. Regulations, including exemptions, for plant-incorporated protectants are addressed in 40 CFR Part 174.
- A nonliquid chemical sterilant, except ethylene oxide, that meets the criteria of 152.6(a)(2) with respect to its claims and 152.6(a)(3) with respect to its use sites is exempted from regulation under FIFRA.

Exemptions for pesticides of a character not requiring FIFRA regulation(40 CFR 152.25)

- Treated articles or substances that meet the specific criteria of 40 CFR 152.25(a), pheromones and pheromone traps, preservatives for biological specimens, foods, natural cedar, and certain minimum risk pesticides <https://epa.gov/node/40897/> listed in 40 CFR 152.25(f)(1) and on the OPP Pesticide Tolerances Website <https://epa.gov/pesticide-tolerances/about-pesticide-tolerances> are exempt.

Pesticides that may be transferred sold or distributed without registration (40 CFR 152.30)

- A pesticide transferred between registered establishments operated by the same producer. (40 CFR 152.30(a))
- A pesticide transferred between registered establishments not operated by the same producer. (40 CFR 152.30(b))
- A pesticide distributed or sold under an experimental use permit. (40 CFR 152.30(c))
- A pesticide transferred solely for export. (40 CFR 152.30(d)
- A pesticide distributed or sold under an emergency exemption. (40 CFR 152.30(e))
- A pesticide transferred for purposes of disposal. (40 CFR 152.30(f))
- Existing stocks of a formerly registered product. (40 CFR 152.30(g))

AR0000368

Pesticides Intended for Use on Food or Feed

EPA establishes maximum residue levels (tolerances) for pesticides in food, including animal feed, under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>. In the absence of a tolerance covering pesticide residues in a food, that food is considered adulterated and subject to seizure. For this reason, EPA regulations require that all needed tolerances be in place before a FIFRA registration will be granted.

Specifically, if the proposed product labeling bears instructions for use of the product on food or feed crops, or if the intended use of the product results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), the applicant must submit a statement indicating whether a tolerance or an exemption from the requirement of a tolerance has been established by the Agency under section 408 of the FFDCA for the pesticide residues resulting from the proposed use (40 CFR 152.50(i).

If the appropriate tolerances or exemptions are not in place, the application must be accompanied by a petition for establishment of appropriate tolerances or exemptions from the requirement of a tolerance in accordance with 40 CFR Part 180 (40 CFR 152.50(i)). Please refer to Chapter 11 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions> for more detailed information on filing petitions for a tolerance.

Import and Export of Pesticides

FIFRA section 17 <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> contains import and export requirements for pesticides. Except for certain exemptions from the requirements of FIFRA listed under 40 CFR Part 152, Subpart B, FIFRA requires that a registration be obtained from EPA before any person in any state or foreign country can sell or distribute any pesticide in the United States.

Pesticides produced by foreign manufacturers and imported for sale or distribution in the United States must comply with all requirements applicable to domestic producers. This includes registering the pesticide product (follow the guidance in Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>) and obtaining an EPA Pesticide-Producing Establishment number before starting production (follow the guidance in Chapter 14 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>). In addition, regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices (EPA Form 3540-1) <https://epa.gov/compliance/epa-form-3540-1-notice-arrival-pesticides-and-devices> for review and determination as to whether the shipment should be sampled and/or permitted entry into the United States.

Technical materials may be imported without registration in sufficient quantities to formulate a pesticide for which an Experimental Use Permit has been granted if the EUP application cites the planned import (40 CFR 172.7). Per 40 CFR 152.30(e). The unregistered product must be labeled in accordance with 40 CFR Part 156.

FIFRA section 17 states that no pesticide, device, or active ingredient used in producing a pesticide solely for export to any foreign country shall be deemed in violation of FIFRA when prepared or packaged to the specifications or directions of the foreign producer, except that producers of such pesticides, devices, and active ingredients are subject to FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> provisions on labels and labeling (section 2(p)) and misbranding (sections 2(q)(1)(A), (C), (D), (E), (G), and (H); 2(q)(2)(A), (B), (C)(i) and (iii); and (D), 7 and 8).

FIFRA section 17(a)(2) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> and its interpretation in 40 CFR 168.75 further state that before the export of any pesticide not registered under section 3 or sold under section 6(a)(1) of FIFRA, the foreign purchaser must have signed a Prior Informed Consent statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under FIFRA. The purchaser must transmit a copy of that statement to an appropriate official of the government of the importing country. Refer to 40 CFR Part 168, Subpart D, for more information. Related information can also be found at the pesticides International Activities Website <https://epa.gov/pesticides/international-activities-related-pesticides>.

Types of Pesticide Registration

Any company wishing to sell its own pesticide product must either:

- obtain a federal registration for its own product; or
- become a supplemental registrant (often termed a supplemental distributor or sub-registrant) for a product that is already federally registered.

These types of registrations, together with amendments to a registration, are described in more detail below. Before submitting a registration request to EPA, the company must obtain a company number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>.

Obtaining a Registration for a Pesticide Product

An applicant who wishes to obtain a registration for its own pesticide product is responsible for submitting or citing all of the information and data that are required to support the registration. The information required includes:

- forms,
- proposed product labeling,
- technical and scientific data that meet the data requirements related to the specific product the applicant intends to produce, and
- statement of how the applicant will comply with any data compensation requirements.

Registrant Summary of Pesticide Petitions for EPA's Notice of Filing <https://epa.gov/pesticide-registration/pesticide-registration-manual-registrant-summary-pesticide-petitions-epas> provide a company with the ability to electronically prepare a pesticide tolerance petition for submission to EPA.

Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product> contains detailed instructions on how to submit an application for pesticide registration.

AR0000370

Obtaining a Supplemental Registration to Distribute a Product Registered by Someone Else

An applicant who does not wish to register and produce its own unique product may become a supplemental registrant for another company that has already registered a product. This supplemental registration allows the new registrant to market the product under its own company and brand name. To use the supplemental registration process, both parties (the original registrant and the supplemental distributor) must:

- enter into an agreement with one another,
- complete and file a Notice of Supplemental Distribution of a Registered Pesticide Product (EPA Form 8570-5) <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms> with EPA, and
- ensure that the supplemental product bears the identical label language apart from the exceptions listed at 40 CFR 152.132(d). Two of the exceptions include the supplemental label utilizing a different product name and the supplemental distributor's name and address instead of the registrant's.

Refer to Chapter 9 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered> for detailed instructions on how to submit an application for supplemental distribution of a pesticide product.

Amending the Registration of a Product Already Registered with EPA

If a registrant has a product previously registered with EPA and wishes to make a change to the registration such as change the formulation or labeling text (i.e., add, delete, or change formulation components or label precautionary statements, or add or change uses), it must file an application to amend its registered product.

Refer to Chapter 6 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide> for detailed instructions on how to submit an application for amended registration of a pesticide product. There are certain changes that registrants may make that do not require an amendment application, but simply require that registrants notify the Agency of the change, and other changes that require no notification at all. Notifications are discussed in Chapter 7 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation> and in PR Notice 98-10 <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments>.

Unconditional/Conditional Registration

EPA has discretion to make pesticide registration decisions under either the unconditional registration criteria of FIFRA section 3(c)(5) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> or the conditional registration criteria of FIFRA section 3(c)(7). These are described below.

Unconditional Registration

An application will be approved under the unconditional registration criteria only if EPA has (as listed in 40 CFR 152.112):

AR0000371

- determined that the application was complete and was accompanied by all materials required by FIFRA, including but not limited to, evidence that the applicant had complied with the data compensation requirements;
- reviewed all relevant data in its possession;
- determined that no additional data were necessary to make the determinations required under FIFRA section 3(c)(5) with respect to the subject product;
- determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data were required;
- determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;
- determined that the product was not misbranded as defined by FIFRA section 2(q) and 40 CFR Part 156;
- determined that, if the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues of any active or inert ingredient of the product in or on food or animal feed, all necessary tolerances or exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA section 408, section 409, or both; and
- been notified by the FDA that the product complies with any requirements imposed by FDA if the product, in addition to being a pesticide, is a drug within the meaning of FFDCA section 201(q).

Unconditional registrations can be granted for a variety of applications – such as identical/substantially similar (me-toos) (described below), new uses, or new active ingredients – so long as all criteria above are met.

Conditional Registration under FIFRA 3(c)(7)

EPA may conditionally approve an application for registration or amended registration of a pesticide product. This may occur if EPA determines that, while a registration decision can be made, further data, studies, or action by the registrant are required by EPA. This section further details how EPA grants a conditional registration depending on whether it is a new active ingredient, a new use, or an Identical/Substantially Similar (formerly "Me Too") product.

Identical/Substantially Similar (Formerly Me-Too) Products:

EPA may conditionally approve an application for registration or amended registration of a pesticide product under FIFRA section 3(c)(7)(A) if the Agency determines that:

AR0000372

- it possesses all data necessary to make the determinations required by FIFRA section 3(c)(7)(A) with respect to the pesticide product that is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);
- the pesticide and proposed uses are identical or substantially similar to any currently registered pesticide and its uses, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment (See 40 CFR 152.113(b)); and
- approving the registration or amendment in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment (40 CFR 152.113(a)(2)).

Each registration issued under 3(c)(7)(A) must submit or cite the same data that would be required for unconditional registration of a similar product under FIFRA section 3(c)(5).

These data must be submitted or cited no later than the time that the data are required to be submitted for similar pesticide product(s) already registered. If a notice requiring these data has been issued under FIFRA section 3(c)(2)(B) before the application has been approved, the applicant must submit or cite those data at the time specified in the notice.

New Uses: EPA may conditionally amend the registration of a pesticide to permit additional uses, even if the data concerning the pesticide may be insufficient to support the unconditional registration, if the Agency determines under FIFRA section 3(c)(7)(B) that:

- the applicant has submitted satisfactory data pertaining to the proposed additional use,
- amending the registration would not significantly increase the risk of any unreasonable adverse effect on the environment, and

Each registration issued under 3(c)(7)(B) must submit or cite the same data that would be required for unconditional registration of a similar product under FIFRA section 3(c)(5).

Note: If an applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated (such as data required by a data call-in issued by EPA under FIFRA section 3(c)(2)(B)), the Agency may amend the registration to require the submission of those data at the same time that the data are required to be submitted with respect to similar pesticides already registered (FIFRA section 3(c)(7)(B)).

New Active Ingredients: EPA may conditionally register a pesticide containing an active ingredient not in any currently registered product for a period reasonably sufficient for the generation and submission of data necessary for registration under FIFRA section 3(c)(7)(C) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, if the Agency determines that:

AR0000373

- insufficient time has elapsed since the imposition of the data requirement for those data to be developed, on the condition that when the Agency receives such data that they do not meet or exceed risk criteria stated in the regulations issued under FIFRA and other conditions issued by the Agency;
- the use of the pesticide during such period will not cause any unreasonable risk to the environment; and
- the use of the pesticide is in the public interest.

Note: Additional requirements for conditional registration of new active ingredients are found in 40 CFR 152.114(b) and (c).

Pesticides that Do Not Qualify for Conditional Registration:

EPA will not approve the conditional registration of a pesticide product for a new use if (40 CFR 152.113(c)):

- the pesticide is the subject of a Special Review, based on a use of the product that results in human dietary exposure; and
- the proposed new use is for a major food or feed crop, or involves use on a minor food or feed crop for which there is an effective alternative registered pesticide that does not meet the risk criteria associated with human dietary exposure.

Registrant Obligations

Registrants are entirely responsible for their pesticide and pesticide labeling and are required by FIFRA and EPA regulations (40 CFR Part 152 and 169) to:

AR0000374

- ensure that each production facility is registered and has an establishment number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or> (and ensure that any contractor facility they use is registered) (40 CFR 167.20);
- maintain a U.S. mailing address (40 CFR 152.122(a));
- notify EPA of name and/or address changes (if a registrant changes its name and/or address and fails to notify EPA of the change(s) and EPA's good faith attempts to contact the registrant are not successful, EPA will issue in the Federal Register a notice of intent to cancel all of the registrant's products under FIFRA section 6(b)) (40 CFR 152.122(a));
- notify EPA if the authorized agent changes (40 CFR 152.122(b));
- provide information on any adverse effects of a pesticide that have not been previously submitted to the Agency in accordance with FIFRA section 6(a)(2) (40 CFR 152.125);
- ensure that their product labeling is in compliance with FIFRA (FIFRA 2(q) and 40 CFR Part 156);
- ensure that supplemental distributor products and their distributor product labeling are in compliance with FIFRA (40 CFR Part 152.132);
- obtain permission to transfer registration of a product and/or data to another person (40 CFR 152.135); and
- pay the annual pesticide registration maintenance fees <https://epa.gov/pesticide-registration/updated-annual-pesticide-registration-maintenance-fees-2023>.

If a registrant owns the production facility, the registrant must:

- register the establishment number(s) for each production facility (40 CFR 167.20);
- maintain product data records (40 CFR 169.2); and
- report annual production volume (40 CFR 169.2(a)).

Refer to 40 CFR Part 152, Subpart G, and 40 CFR Part 169.

State Pesticide Regulatory Agencies

The registration and use of pesticides are not only regulated by federal laws, but also by state laws and regulations, which differ from state to state. It is advisable to consult with each state and U.S. territory for information on their registration requirements. The National Pesticide Information Center <http://npic.orst.edu/reg/state_agencies.html> provides the telephone numbers and addresses for the primary pesticide regulatory agency in each state and U.S. territory.

AR0000375

Enforcement and Compliance

EPA's regulatory oversight of pesticides manufactured in, imported to, and/or used in the United States includes not only the science-based review and decision-making process performed by the Agency's Office of Pesticide Programs but also oversight to ensure compliance with federal laws and regulations related to pesticides. These efforts are conducted by EPA's Office of Enforcement and Compliance Assurance (OECA) <https://epa.gov/compliance/federal-insecticide-fungicide-and-rodenticide-act-compliance-monitoring>.

Contacts for Additional Information

The following chapters of this manual are intended to provide detailed information regarding the pesticide registration process and obligations of applicants and registrants during that process. However, if during the registration process you require additional information or clarification concerning a pending application for registration, contact the Product Manager assigned to the pesticide in your product. A listing of Product Managers and a sampling of the pesticides they are responsible for can be found in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

For questions of a general nature that do not pertain to any specific pesticide, or pertain to a new pesticide active ingredient not yet applied for, contact the respective Ombudsman for the type of pesticide (i.e., conventional chemical, biopesticide, or antimicrobial) for which you have a question. A listing of the various Ombudsmen can be found in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

If you have any questions concerning devices, including whether they are subject to FIFRA or how to register an establishment, please contact:

> U.S. EPA
> Toxics and Pesticides Enforcement Division
> 1200 Pennsylvania Avenue, N.W. (2245A)
> Washington, D.C., 20460-0001
> Email: OPPDeviceDeterminations@epa.gov

References Cited in Chapter 1

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

To find current Code of Federal Regulations citations, use the e-CFR.

Code of Federal Regulation, Title 40

AR0000376

- Part 152 - Pesticide Registration and Classification Procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 158 - Data Requirements for Registration
- Part 168 - Statements of Enforcement Policies and Interpretations
- Part 169 - Books and Records of Pesticide Production and Distribution
- Part 172 - Experimental Use Permits
- Part 180 - Tolerances and exemptions from tolerances for pesticide chemicals in food

Code of Federal Regulation, Title 21

- Part 182 - Substance generally recognized as safe

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 2 - Definitions
- Section 3 - Registration of pesticides
- Section 6 - Administrative review; suspension
- Section 7 - Registration of establishments
- Section 8 - Books and Records
- Section 17 - Imports and Exports

Federal Food, Drug and Cosmetic Act <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>

- Section 201 - Definitions
- Section 408 - Requirement for Tolerance or Exemption

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

- Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>
- Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>
- — Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>
- — Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>
- — Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>
- — Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>
- Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>
- — Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>
- — Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
- — Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023

AR0000378



AR0000379

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

AR0000381

An official website of the United States government

Pesticide Registration Manual: Chapter 2 – Registering a Pesticide Product

In this chapter:

- Registering a Pesticide Product
  - Pre-Registration Meeting
- General Pesticide Categories
- Reduced Risk Pesticides
- Examples of Pesticide Registration Applications
  - New Chemical or New Active Ingredient
  - New Use
  - Identical/Substantially Similar (Formerly “Me-Too”) Product
- Required Contents of the Application Package
  - Administrative Portion of the Application Package
  - Data Portion of an Application Package
  - Child-Resistant Packaging (CRP) Certification
  - Restricted Use Pesticide (RUP) Classification
  - Statement Concerning Tolerances
- Registration Procedures
  - Pesticide Registration Notice 11-3
  - Completeness Reviews
  - Applications for Registration That May Qualify as Identical/Substantially Similar (Formerly “Me-Too”) Products
  - How to Submit an Identical/Substantially Similar Product Application
  - Where to Submit an Application for Registration
  - Electronic Submissions
- Contacts for Additional Information
- References Cited in Chapter 2

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>
2. **Registering a Pesticide Product**

Registering a Pesticide Product

This chapter discusses what information must be submitted to the Agency when applying for a pesticide product registration. The chapter also outlines how the process for reviewing pesticide applications can vary based on what type of pesticide is being registered and that chemical's or product's previous registration history. This chapter also discusses the importance of correctly formatting data submissions to avoid delays or rejection of application packages.

Registrant Summary of Pesticide Petitions for EPA's Notice of Filing <https://epa.gov/pesticide-registration/pesticide-registration-manual-registrant-summary-pesticide-petitions-epas> provide a company with the ability to electronically prepare a pesticide tolerance petition for submission to EPA.

Pre-Registration Meeting

The Agency welcomes requests for a pre-registration meeting. This type of meeting can provide useful guidance to the applicant regarding information needed for registration. Applicants are encouraged to contact the appropriate branch (see Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>) assigned to the active ingredient in their product before submitting an application for registration. Contact the ombudsman for the division <https://epa.gov/node/46259/> if the appropriate branch is unknown.

General Pesticide Categories

EPA separates pesticides into three general categories. Based on which type of pesticide is being reviewed for a pesticide registration decision, different divisions of EPA's Office of Pesticide Programs will evaluate the action, and the data requirements for registration will vary.

The three general categories of pesticides are:

3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

AR0000384

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- Conventional chemical pesticides.
- Biopesticides.
- Antimicrobial pesticides.

Conventional pesticides are generally synthetic chemicals used predominantly to kill insects, weeds, and fungi.

Biopesticides include naturally occurring substances that control pests (biochemical pesticides <https://epa.gov/pesticides/biopesticides>), microorganisms that control pests (microbial pesticides), and pesticidal substances produced by plants containing added genetic material (plant-incorporated protectants or PIPs <https://epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-plant-incorporated-protectants>).

Antimicrobial pesticides are substances or mixtures of substances intended to destroy or suppress the growth of harmful microbiological organisms, and pesticides that protect inanimate objects and surfaces from organisms such as bacteria, viruses, or fungi. See FIFRA section 2(mm).

The three divisions of EPA's Office of Pesticide Programs that review applications to register a pesticide or product and the types of product review they oversee are:

- Registration Division (RD) for conventional chemicals <https://epa.gov/node/50781/>.
- Biopesticides & Pollution Prevention Division (BPPD) for biopesticides and plant-incorporated protectants <https://epa.gov/node/50763/>.
- Antimicrobials Division (AD) for antimicrobial pesticides <https://epa.gov/node/50759/>.

This chapter provides the basic information on registering any type of pesticide. However, additional information on the unique nature of biopesticides and antimicrobials is available in other chapters:

- Chapter 3 provides additional detailed information on registration requirements for biopesticides <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>.
- Chapter 4 provides additional detailed information on registration requirements for antimicrobial pesticides <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>.

Reduced Risk Pesticides

FIFRA section 3(c)(10)(B) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> provides for expediting the review of certain types of applications for registration. This program is referred to as the Conventional Reduced Risk Pesticide Program <https://epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program>. The Reduced Risk

program expedites the review and regulatory decision-making process of conventional pesticides that meet one or more of the following criteria:

- Reduce the risks of pesticides to human health.
- Reduce the risks of pesticides to non-target organisms.
- Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.
- Broaden the adoption of integrated pest management strategies, or make such strategies more effective.

Expediting registrations for pesticides considered to be reduced risk ensures that these reduced risk pesticide uses get into the marketplace and are available to growers and users as soon as possible. For more information, see the Conventional Reduced Risk Pesticide Program <https://epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program> Web page.

This program does not apply to biological or antimicrobial pesticides, which are handled through separate expediting processes.

Examples of Pesticide Registration Applications

In addition to the three broad categories of pesticide type described above that influence the registration process, EPA also takes into consideration the previous regulatory history of a pesticide registration application. New pesticide products and uses are further delineated in the following manner:

New Chemical or New Active Ingredient

“New Chemical” or “New Active Ingredient” is an Agency term that refers to a pesticide registration application for a product that contains a pesticide active ingredient that is not contained in any other pesticide product currently registered with the Agency.

New Use

A “New Use” pesticide registration application amendment refers to adding a use for previously registered active ingredient(s), where the requested use is not currently included in the labeled directions for use of any product that contains the active ingredient(s). New uses are defined in 40 CFR 152.3 as follows:

AR0000387

1. Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of a tolerance or food additive regulation (please refer to Chapter 11 for a discussion of tolerances <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>).
2. Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern.
3. Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

Identical/Substantially Similar (Formerly "Me-Too") Product

An "Identical/Substantially Similar" pesticide registration application refers to a request to register a new pesticide product that is:

- identical in its uses and formulation; or
- substantially similar in its uses and formulation to one or more products that are currently registered and marketed in the United States; or
- differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

This section discusses only new "identical/substantially similar" product registrations. See:

- Chapter 6 of this document for a discussion of "identical/substantially similar" amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>.
- Chapter 10 for discussion of data compensation issues for both <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>.

Common terms used for some "identical/substantially similar" products are:

- Identical Repack Registrations – A complete (100%) repackaging of an identical, already-registered product, where an identical label is used for the product other than name, address, name of product, and registration number.
- Old Chemical New Product Registrations – A previously registered active ingredient that is being reformulated to make a new product with the same use pattern as the registered active ingredient. (Note: the applicant will be required to explain how the labeling has been derived and justify certain aspects of the labeling. This is fully explained in Chapter 10 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>.)

Important Note: The following examples illustrate when an application is not considered to be an "identical/substantially similar" product. These are differences between the currently registered product and the application for registration:

AR0000388

- the maximum use rate of the product is increased beyond that which is currently registered;
- a pre-harvest interval (PHI) is changed; or
- any other changes are made that might affect the pesticide residues in food or feed commodities or exposure to non-target organisms.

Other examples are provided in the section titled “Review of Applications for Identical/Substantially Similar (Formerly “Me-Too”) Products." Also note that for “identical/substantially similar” product applications, the source (producer or manufacturer) of the active ingredient must be registered. A product with an unregistered source will not be considered an “identical/substantially similar” product.

Required Contents of the Application Package

A pesticide registration application for a new product must include certain types of information regarding the applicant as well as the pesticide product and comply with fee requirements. Application requirements described here are derived from regulatory requirements codified in 40 CFR 152.50 (Contents of Application) and section 33 of FIFRA as amended by the Pesticide Registration Improvement Extension Act (PRIA 3) <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>, which established registration service fees.

When EPA receives the application and the applicable fee required by PRIA 3 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>, the Agency will screen the application during a 21-day period to determine if it contains all required forms, labeling, and data formatted as described in the Agency’s guidance (PR Notice 11-3), and documentation of fee payment <https://epa.gov/pria-fees>. The fee payment documentation may include a request for a fee reduction or waiver <https://epa.gov/pria-fees/appeals-fee-and-waiver-decisions> or an exemption <https://epa.gov/pria-fees/guidance-ir-4-exemptions>. Any deficiencies identified during the 21-day Content Screen and uncorrected by the applicant may lead to the Agency’s rejection of the application and retention of 25% of the fee.

After the 21-day Content Screen, PRIA 3 requires that a Preliminary Technical Screen be conducted within 45 days after the PRIA start date for submissions with PRIA decision review timeframes ≤6 months and within 90 days for submissions with PRIA decision review timeframes > 6 months. The purpose of the preliminary technical screen is to determine if the pesticide registration application and accompanying information and data are:

1. accurate and complete;
2. consistent with proposed labeling and any tolerance or tolerance exemption, and
3. such that subject to full review could result in the granting of the application.

If the application fails the technical screen, and the deficiencies cannot be corrected by the applicant within 10 business days after receipt of the Agency’s notification of deficiencies, the Agency will reject the application and provide the appropriate refund, if warranted.

If applicants have any questions or concerns about the completeness of their application, the Agency strongly encourages applicants to contact the appropriate registration Ombudsman before submitting the application.

AR0000389

Aside from the applicable fee (and fee waiver or exemption request, if any), an application consists of required elements that should be organized into two parts:

- administrative information; and
- data.

Administrative Portion of the Application Package

The administrative portion of an application consists of the following documentation:

Fee Payment

For PRIA 3-covered applications, documentation or certification of fee payment should be the first page of or on the front of an application. The cover letter, application form, etc., should be underneath it to enable the Agency to match a payment with an application. Certification of payment may be:

- a copy of the check or pay.gov acknowledgement; or
- a request for an exemption from registration service fees.

Small business and minor use fee reductions or waiver requests should accompany the certification of payment as a document that can be separated from the rest of the application. Only applications received with a certification of payment will enter the review process.

Note: Applicants are required to pay the Agency 25% of the applicable fee even if an application is withdrawn or rejected for failure to pay a fee.

Cover Letter

A cover letter is not required but is highly recommended. The cover letter should state the general purpose of the submission and identify each item in the application package. It should also contain the email address of the applicant in order to receive the Agency's PRIA registration milestone tracking emails.

Application Form

Complete and submit an original Application for Pesticide Registration/Amendment form (EPA Form 8570-1 (PDF) <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms> with each application for registration. 40 CFR 152.50(a).

Detailed instructions on completing the application form are provided on the back of the form and summarized in this chapter. These instructions also specify the number of copies of each item in an application package that needs to be submitted. It is important to read and follow these instructions and provide complete and accurate information.

AR0000390

- Tip: Remember to sign and date the application form.

Identity of the Applicant

Name of the Applicant: Applicants must identify themselves. An applicant not residing in the United States must also designate a U.S. agent (see below) to act on its behalf on all registration matters. 40 CFR 152.50(b)(1).

Address of Record: Applicants must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and EPA will send notices imposing legal requirements and correspondence concerning the application and any subsequent registration information to that address. 40 CFR 152.50(b)(2).

- It is the responsibility of the applicant or registrant to ensure that EPA has a current and accurate address. Refer to Chapter 21 for how to notify the Agency of a change in address <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

Important Note: If the Agency's good faith attempts to contact the applicant are not successful, the Agency will issue in the *Federal Register* a notice of intent to cancel all of the applicant's registered products under FIFRA section 6(b) (refer to 40 CFR 152.122).

Authorized Agent: Any applicant may designate a person residing in the United States to act as its agent. 40 CFR 152.50(b)(3). Applicants not residing in the United States must designate a U.S. agent to act on their behalf on all registration matters. 40 CFR 152.50(b)(1).

For list of agents see: List of Pesticide Regulatory Consultants <https://epa.gov/pesticide-registration/list-pesticide-regulatory-consultants>.

An applicant who designates an agent must send a letter to the Agency stating the name and U.S. address of the agent. Applicants must also notify the Agency if they change their designated agent. An applicant may terminate a designated agent at any time by notifying the Agency in writing.

The Agency treats authorized agent notifications in the same way as company name and address changes. (See Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>).

Company Number: If an applicant has been assigned a company number by the Agency, the application must reference that number.

Summary of the Application: Each application must include a list of the data submitted with the application, together with a brief description of the results of the studies. The list of data submitted may be the same as the list required by 40 CFR 158.32. The summary must state that it is releasable to the public after registration in accordance with 40 CFR 152.119.

Identity of the Product: The product for which the application is being submitted must be identified as follows:

- the product name;
- the trade name(s) (if different); and
- the EPA Registration Number, if currently registered.

Draft Labeling: Section 2(p)(1) of FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> defines the written, printed or graphic material on, or attached to, the pesticide or device or any of its containers or wrappers." The term "labeling" is defined as "all labels and all other written, printed, or graphic matter –

A. accompanying the pesticide or device at any time; or
B. to which reference is made on the label or in literature accompanying the pesticide or device." (See FIFRA section 2(p)(2) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>).

It is unlawful to sell or distribute a pesticide if any claims made for it differ from claims made on labeling required for registration. (See FIFRA section 12(a)(1)(B) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>) Therefore, advertising claims for a pesticide product must not contradict claims made in the product's labeling. Labeling requirements are codified in 40 CFR Part 156.

Labeling includes detailed information including the ingredients statement, warnings and precautionary statements, and directions for use. EPA has also developed a Label Review Manual <https://epa.gov/pesticide-registration/label-review-manual> as guidance to its staff on reviewing labels. This manual includes detailed information on content and format of labels and labeling.

Five copies of the proposed draft labeling must be submitted with an application. (See 40 CFR 152.50(e). The draft labeling may be typed or otherwise printed but must be legible, reproducible, and on 8-1/2 x 11-inch paper. EPA encourages electronic submission of the label. Applicants should refer to EPA's Web site for the Agency's guidance on submitting an electronic label <https://epa.gov/pesticide-registration/electronic-submission-labels>.

Important Note: Only one complete set of the documents in the administrative portion of an application (as described in the instructions on the application form) is required (40 CFR 152.50(a)). The formal requirements included in PR Notice 11-3 apply to the data portion of an application package only, not to the previously described administrative portion.

Data Portion of an Application Package

Applicants are responsible for citing or generating all data to meet data requirements. The purpose of these data requirements is to demonstrate that the product will not cause unreasonable adverse effects and for pesticides that will need a tolerance or tolerance exemption to demonstrate a reasonable certainty of no harm. These requirements include, as applicable, data on:

AR0000392

- residue chemistry,
- environmental fate,
- toxicology,
- reentry protection,
- spray drift,
- wildlife and aquatic organisms,
- plant protection,
- non-target insects,
- product performance, and
- product chemistry.

Data requirements in support of applications for registration of a pesticide product are specified in 40 CFR Part 158 and for antimicrobial active ingredients and products in 40 CFR Part 161.

The data submitted in support of a registration must be formatted according to the requirements detailed in 40 CFR 158.32-34. See FIFRA section 33((f)(4)(B)(iii)(II) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>. Please refer to the section "Pesticide Registration Notice 11-3" later in this chapter and also Chapter 15 of this manual <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>for additional guidance on how to format a data submission.

- Tip: Currently, three identical copies of all applicable data required to support the registration of a product must be submitted with an application. Alternatively, data may be submitted electronically as described in the electronic submission guidance <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>.

Confidential Statement of Formula

Two copies of a Confidential Statement of Formula (EPA Form 8570-4 (PDF) <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) must be completed and submitted with each application for registration. See FIFRA section 3(c)(1)(D), 40 CFR 152.50(f) and 40 CFR 158.320. Detailed instructions for completing the form and providing acceptable information are provided on the back of the form. Additional information can be found in 40 CFR 158.300-355.

Important Note: The Confidential Statement of Formula (CSF) is Confidential Business Information (CBI) and should not be transmitted over FAX machines or through electronic submission such as email unless senders want to waive their CBI rights. If you wish to waive these rights, this should be clearly stated on the CSF.

A Confidential Statement of Formula must include

- all active ingredients;
- all inert ingredients;
- all impurities of toxicological significance associated with the active ingredient; and
- all impurities found to be present at a level equal to or greater than 0.1 percent by weight of the technical grade active ingredient. See 40 CFR 158.320.

In addition, all inert ingredients that are used in a product with food uses must have a tolerance or exemption from a tolerance. (Please refer to Inert Ingredients in Chapter 8 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>.) See Appendix A <https://epa.gov/pesticide-registration/pesticide-registration-manual-confidential-statement-formula-documents> for additional guidance on CSF issues.

Product Chemistry and Acute Toxicology Data

If a product is **not** substantially similar to another registered product, the applicant is required to submit, at a minimum, product chemistry and acute toxicity data for the product.

Type of Pesticide	Product Chemistry	Acute Toxicology
Conventional	40 CFR Part 158, Subpart D	40 CFR 158.500
Biopesticide	40 CFR Part 158, Subpart U and V	40 CFR Part 158, Subparts U and V
Antimicrobial	40 CFR Part 158, Subpart W	40 CFR Part 158, Subpart W

Additional information can be found in the OPPTS Harmonized Test Guidelines, Series 830 <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/series-830-product-properties-test-guidelines> (Product Chemistry) and 870 (Toxicology) <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/series-870-health-effects-test-guidelines>. Additional guidance concerning product chemistry and CSF issues can be found in Appendix A <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>.

If the source of the active ingredient used to formulate the final product is not an EPA-registered source, the applicant must provide, at a minimum, product chemistry data and acute toxicity data on the technical grade of the active ingredient in addition to the data for the formulated product.

Products Substantially Similar or Identical to Registered Products

At the very minimum, applications for products that claim to be substantially similar to other registered products must submit or reference the product-specific chemistry data, which are discussed in detail in 40 CFR 158.300-355, 40 CFR 158.2030, 40 CFR 158.2120 to determine if products are substantially similar. No product chemistry data are required to be submitted for identical products, i.e., 100% repackage of a currently registered product. View 40 CFR Part 158.

- Under a self-certification program begun in 1998, product chemistry information may be submitted in summary form for qualifying products. Refer to PR Notice 98-1 <https://epa.gov/node/63243/> for details.

AR0000394

Efficacy Data (Product Performance Data)

Efficacy data are routinely required to be submitted to support products that control pests of public health significance, including but not limited to products to control:

- Pathogenic bacteria.
- Viruses.
- Mosquitoes.
- Ticks.
- Roaches.
- Fleas.
- Rats.
- Mice.

Efficacy data requirements related to these types of pest control products are detailed at 40 CFR 158.400, 40 CFR 158.2070, 40 CFR 158.2160 and 40 CFR 158.2220. View 40 CFR Part 158.

Also, refer to the OPPTS Harmonized Test Guidelines, Series 810 <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines> and Antimicrobial Science Policies <https://epa.gov/pesticide-registration/antimicrobial-policy-and-guidance-documents>.

Although efficacy data (product performance data) are not routinely required to be submitted for most insecticide, fungicide, or herbicide products, the applicant or registrant must conduct efficacy tests on each of its products in order to ascertain through testing that the product performs in accordance with its labeling and use directions claims.

- Efficacy data may be required to be submitted on a case-by-case basis and must be kept in the applicant's or registrant's files.

Generic Data

Generic data pertain to the active ingredient and not to the formulated end use pesticide product. These data must be submitted or cited for applicable new uses, products not formulated with a registered product, and new chemicals. These requirements include data on:

AR0000395

- residue chemistry;
- environmental fate;
- toxicology;
- wildlife and aquatic organisms;
- plant protection; and
- non-target insects.

Specific data requirements in support of applications for registration of a pesticide product are specified in 40 CFR Part 158.

- If the Selective Method (40 CFR 152.90) of data support is used, the Data Matrix Form <https://epa.gov/node/37487/>is used to show the data and corresponding EPA Master Record Identifier (MRID) numbers. When using the Cite-all Method (40 CFR 152.86) of data support, applicants must use the Data Matrix to list companies to whom they have made offers to pay. Definitions of the different types of data support are also found in Chapter 10 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>.

Data Compensation Requirements

FIFRA section 3(c)(1)(F) and its implementing regulations require that applicants applying for registration of a pesticide comply with data compensation procedures. This means that if an applicant decides to use data previously generated by another registrant in support of its own product registration, the applicant generally is required to offer payment to that original data submitter and in some cases must obtain permission to cite such data. See FIFRA section 3(c)(1)(F) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> and 40 CFR Part 152, Subpart E.

Normally, one or more of the following three data compensation forms are required to be submitted with an application for registration:

AR0000396

- A properly completed Certification with Respect to Citation of Data (EPA Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) must accompany any application for which data are being submitted or cited.
- A properly completed *Data Matrix* must accompany any applications (EPA Form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) for which data are being submitted or cited under the selective method. Applicants should also use a Data Matrix when using the cite-all method for purposes of listing the persons to whom offers of compensation have been made.
- A properly completed *Formulator's Exemption Statement* (EPA Form 8570-27 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) must accompany any application (required only when utilizing the formulator's exemption)

These requirements and applicable forms are fully discussed in Chapter 10 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements> of this manual. For further reference, see FIFRA section 3(c)(1)(F) and 40 CFR 152.80 - 152.99.

Data Waivers

A waiver of data requirements may be warranted when the Agency determines that certain data that would otherwise be required are not needed.

EPA will consider waiver requests for specific data requirements. Applicants must demonstrate in writing that a specific data requirement is unnecessary for their product. The waiver request should be accompanied by all of the pertinent information including copies of the references cited by the applicant.

There is often confusion as to what constitutes a data waiver. For example, regulations can state that certain data requirements are not applicable to a category of products (such as some footnoted items in the Data Requirement Tables in 40 CFR Part 158. These circumstances are not considered data waivers.

In some cases data requirements may be fulfilled because other data can be substituted to fulfill the data requirement. For example, an applicant could submit studies done by the paint industry, or threshold levels determined by NIOSH/OSHA, to fulfill the requirement for inhalation toxicity data for the product. In this situation, data are required, but are already available from an existing source. Using data from such a source is not a waiver of data requirements.

Thus, the term waiver is limited to those cases where data would ordinarily be required, but are not required in the given case because of an Agency determination that the data are not needed. Additionally, if the applicant or registrant believes a data requirement is not appropriate for its product, it should consider submitting a request for a data waiver.

Rationale for a Data Waiver

A waiver from a particular data requirement specified in 40 CFR Part 158 as applicable to a category of products, may be requested for an individual product in that category if that product has special features that make the development of such data inappropriate.

For example, some products may have unusual physical, chemical, or biological properties or atypical use patterns that would make a particular data requirement inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks of the product. In these

AR0000397

cases the Agency may waive data requirements that it finds are inappropriate but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards. It is the applicant's responsibility to provide compelling, substantiated information in the request for a data waiver.

The applicant may, under 40 CFR 152.91, demonstrate compliance for a data requirement by:

- claiming that a waiver previously granted by the Agency also applies to a data requirement for its product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an applicable Reregistration Eligibility Decision (RED) document and must explain why that waiver should apply to its product; or
- requesting and being granted a new waiver to satisfy the data requirement.

Procedures for Submitting Data Waiver Requests

To request a data waiver, the applicant must submit a written request which should accompany their PRIA registration application. Certain data waiver requests require a registration service fee. See Chapter 5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>.

- Tip: Applicants who plan to request a data waiver should discuss their plans with the EPA staff person responsible for their product before developing and submitting extensive support information for the request.

The waiver request must specifically identify the data requirement for which a waiver is requested and must provide specific information relative to each requirement for the compound in question, explaining why the applicant thinks the data requirement(s) should be waived.

The specific waiver must allow the Agency to determine if the kind and levels of exposure resulting from the proposed use may allow waiver of the ordinarily required data. In all cases, the Agency needs scientifically sound information to make a decision on specific data waiver requests. Simply stating that a product is ubiquitous in nature or is Generally Recognized as Safe (GRAS) is insufficient.

A Waiver Request May Include:

- description of unsuccessful attempts to generate the required data;
- other information the applicant believes would support the request; and
- suggestions of alternative means of obtaining data to address the concern that underlies the data requirement.

AR0000398

For example, to support a waiver for inhalation toxicity data, an applicant might submit information showing that the product is of a nature that precludes the potential for inhalation exposure.

Notice of Agency Decisions on Data Waiver Requests

EPA will review each data waiver request and inform the applicant in writing of its decision. For decisions that could apply beyond a specific product, the Agency may choose to send a notice to all registrants or to publish a notice in the Federal Register announcing its decision.

Agency decisions on data waiver requests will be available to the public at the Office of Pesticide Programs' Docket Reading Room, 2777 Crystal Drive, S-4400, Arlington, VA 22202. The telephone number is 703-305-5805. Hours are from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

- An Agency decision denying a written request to waive a data requirement shall constitute final Agency action for purposes of FIFRA section 16(a).

Child-Resistant Packaging (CRP) Certification

The criteria for which products require child-resistant packaging are available at 40 CFR 157.20 – 157.36.

If a product meets the criteria requiring child-resistant packaging, the applicant must submit a certification (see 40 CFR 157.34) that the packaging to be used for the product meets the child-resistant packaging standards described in 40 CFR 157.32.

The certification must contain the following information:

1. The name and EPA registration number of the product to which the certification applies, the registrant's name and address, the date, and the name, title and signature of the company official making the certification.
2. A statement that the packaging that is being used for the product will meet the standards of 40 CFR 157.32. The statement, “I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32,” will suffice for this purpose.

Also see PR Notice 97-9 <https://epa.gov/node/63243/> and PR Notice 96-2 <https://epa.gov/node/63243/> and Child-Resistant Packaging <https://epa.gov/pesticide-registration/child-resistant-packaging-pesticides> Web page.

Restricted Use Pesticide (RUP) Classification

EPA has classified some or all of the uses of certain pesticides as “Restricted Use.” The "Restricted Use" classification restricts a product, or its uses, to use by a certified pesticide applicator or under the direct supervision of a certified applicator. (For detailed information on the "Restricted Use" Classification, consult 40 CFR Part 152, Subpart I, 152.160 – 152.171). See 40 CFR Part 171 for more information on certification of pesticide applicators.

AR0000399

- Tip: Criteria used for determining whether a product requires the restricted use classification can be found in 40 CFR 152.170.
- More information on restricted use pesticides <https://epa.gov/pesticide-worker-safety/restricted-use-products-rup-report>.

Statement Concerning Tolerances

If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide residues in or on food or feed, the applicant must submit a statement indicating whether such residues are authorized by a tolerance, exemption from the requirement of a tolerance, or food additive regulation issued under section 408 or 409 of FFDCA. If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances, exemptions from the requirement of a tolerance, or food additive regulations, in accordance with 40 CFR Part 180.

Registration Procedures

Procedures for submitting a complete application for registration of a pesticide product are detailed in regulations at 40 CFR 152.40-152.55 (entitled Registration Procedures).

A separate application for registration must be made for each pesticide product that will be distributed or sold. A pesticide product registration is required for each manufacturing use product or end use formulation.

A manufacturing use product is a product intended and labeled for formulation and repackaging into other pesticide products. A manufacturing use product label does not bear directions for use, but states that the product is for use only in formulating other products. An end-use formulation is a product that bears directions for use on the label.

Alternate Formulations

Any change in formulation must contain the same certified limits for each active ingredient as the basic formulation. Any variation in certified limits of active ingredients in a product requires a separate registration.

The percentages and identities of inert ingredients are allowed to vary as “alternate formulations” as long as these formulations are deemed to be substantially similar to the basic formulation (further information: 40 CFR 152.43 - Alternate Formulation).

- Applicants are responsible for the accuracy and completeness of all information submitted in connection with their applications.

Pesticide Registration Notice 11-3

In a Pesticide Registration Notice issued on July 29, 1986, EPA outlined how data should be submitted for review by the Agency. PR Notice 11-3 contains specific instructions on organizing and formatting submittals of supporting data. It does not address the substance of the test reports <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>.

Common Errors

In an analysis conducted by the Office of Pesticide Programs in 2006, EPA identified common formatting errors of submitted data. These common errors included:

- Incorrectly formatted Confidential Business Information Statement.
- Missing or incomplete Good Laboratory Practice (GLP) Standards Compliance Statement.
- Incorrect pagination.
- Legibility problems.
- Unsigned documents.

Certain forms have been identified that are often missing from the data submission, including the:

- Certification of Data Compensation statement.
- Formulator's Exemption statement.
- Data Matrix Form.

Specific problems with Data Matrix requirements include failure to include all required generic and product-specific data and citing incorrect MRID Numbers.

Important Notes: Following the instructions in PR Notice 11-3 is essential. Taking time to ensure that data submissions follow these formatting guidelines will avoid rejection of the application or submission during PRIA 3's 21-day initial content review.

An application will be rejected if the required three copies of the data are not properly bound and formatted or the electronic submission does not follow Agency guidance. Read more about electronic submission of pesticide applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>.

Completeness Reviews

When EPA receives applications for pesticide registration, there are three steps in processing an application to determine whether the application is complete and contains sufficient information for the Agency to make a regulatory decision. These steps are:

AR0000401

- Initial 21-day Content Screen.
- Preliminary Technical Screen.
- In depth review of data -- data deficiencies or need for additional information identified.

These reviews are described in the next three sections.

Initial 21-day Content Screen

Upon receipt, an application will be assigned a file symbol. A file symbol is a temporary identification number that is a combination of the applicant's company number and a letter, which is the precursor to the product number (ex. 12345-xxx). The Agency then conducts a 21-day initial content screen to determine whether the appropriate fee has been paid and that the application contains the necessary forms, draft labeling, and data formatted in accordance with Agency guidance (e.g., PR Notice 11-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>). Applicants must correct applications within the 21-day initial content review period to successfully complete the screen.

Preliminary Technical Screen

After the 21-day Content Screen, PRIA 3 requires that a Preliminary Technical Screen be conducted within 45 days after the PRIA start date for submissions with PRIA decision review timeframes ≤6 months and within 90 days for submissions with PRIA decision review timeframes > 6 months. The purpose of the preliminary technical screen is to determine if the pesticide registration application and accompanying information and data are:

1. accurate and complete;
2. consistent with proposed labeling and any tolerance or tolerance exemption; and
3. such that subject to full review could result in the granting of the application.

If the application fails the technical screen and the deficiencies cannot be corrected by the applicant within 10 business days after receipt of the Agency's notification of deficiencies, the Agency will reject the application.

In-Depth Review of Data -- Data Deficiencies or Need for Additional Information Identified

Once the application is placed into the Agency's review process, it is reviewed in depth. If during this in-depth review, the Agency determines that there are data deficiencies or that further information is needed in order to complete the Agency's review, the Agency will notify the applicant of the deficiencies per 40 CFR 152.105 and allow the applicant 75 days to make corrections or additions to complete the application. If the applicant believes that the deficiencies cannot be corrected within 75 days, he must notify the Agency within those 75 days of the date on which he expects to complete the application. If, after 75 days, the applicant has not responded, or if the applicant subsequently fails to complete the application within the time scheduled for completion, the Agency will terminate any action on such application, and will treat the application as if it had been withdrawn by the applicant. Any subsequent submission relating to the same product must be submitted as a new application.

If submitting in response to a deficiency letter from EPA, the applicant's submission (on EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) should be marked "Resubmission" at the top of the application form and should include a copy of EPA's deficiency letter.

Read more about application submission and screening <https://epa.gov/pria-fees/application-submission-and-screening>.

Applications for Registration That May Qualify as Identical/Substantially Similar (Formerly "Me-Too") Products

Section 3(c)(3)(B)(ii) of FIFRA requires EPA to review, as expeditiously as possible, applications for registration of products that are "substantially similar" or "identical" in composition and labeling to other EPA-registered pesticide products or would differ in ways that would not significantly increase the risk of unreasonable adverse effects on the environment. In addition, the Agency is required to:

- Conduct an initial contents screen within 21 days of receiving the application and the applicable fee.
- Under PRIA 3 as part of the Preliminary Technical Screen, any similarity claim is evaluated by the EPA. The applicant is allowed 2 attempts to identify an already registered product that is substantially similar to the proposed product. If after the second attempt the applicant fails to identify a substantially similar product, the application is rejected, and no refund of the PRIA fee is granted.

Applications for Registration That May Qualify as Identical/Substantially Similar (Formerly "Me-Too") Products

For "Identical/substantially similar" applications, the applicant must provide the EPA registration number of the currently registered product that is believed to be "substantially similar" or "identical" to the proposed product.

Examples of end-use "identical/substantially similar" new product applications that may qualify as an identical/substantially similar product include:

- Applicant references substantially similar, registered pesticide product with no data review or only review of Product Chemistry data with cite-all data citation, or selective citation where the applicant owns all the required data (or the applicant submits a specific authorization letter from the data owner).
- Applicant references substantially similar, registered pesticide product with no data review or only review of Product Chemistry or selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where the applicant does not own all required data and does not have a specific authorization letter from data owner.
- Applicant is repackaging a registered product that does not require the submission of data nor the submission of a data matrix.

Applications That Do Not Qualify as Identical/Substantially Similar New Products

Examples of end-use "identical/substantially similar" new product applications that may not qualify as an identical/substantially similar product include:

- inert ingredients that do not currently exist in any other pesticide formulation;
- a reference to a canceled product <http://npirspublic.ceris.purdue.edu/ppis/>;
- significant changes in the percentage of active ingredient;
- new formulation types;
- directions for controlling new, nonpublic health pests;
- directions for new dosage rates;
- directions for different frequency and timing of applications;
- directions for use in geographical locations other than those previously registered; and
- directions for use on new sites and for new methods of application for the active ingredient or ingredients.

Applications that require review of acute toxicity and efficacy data do not qualify as identical/substantially similar new product applications since submission of such data would indicate that the product is not identical or substantially similar in composition and labeling to the currently registered pesticide identified in the application.

Examples of end-use product applications that do not qualify as an identical/substantially similar include:

- Applicant references similar, registered pesticide product and submits product chemistry and required efficacy for specific formulation purposes.
- Applicant asserts similarity but does not reference a registered pesticide product. Submits product chemistry.
- Applicant references a similar pesticide product and submits product chemistry and required nitrosamine data for a specific formulation.
- Applicant does not reference a pesticide product. Submits product chemistry and required nitrosamine data for a specific formulation.
- Applicant does not reference a pesticide product. Submits product chemistry and the full battery of acute data.
- Applicant references a similar registered pesticide product. Submits product chemistry, the full battery of acute data and required efficacy data.
- Applicant references a pending registration.

Important Note: Applications for new Manufacturing Use Products, including Technical Grade Products, are covered by a number of registration service fee (PRIA) fee categories <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>.

AR0000404

How to Submit an Identical/Substantially Similar Product Application

If it is believed that product application qualifies as an identical/substantially similar new product application, the applicant should submit "Application for Pesticide Registration/Amendment" (EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) and identify – in Section II of the application form – the EPA Registration Number and name of the product to which it believes the product is substantially similar or identical.

Where to Submit an Application for Registration

Please refer to Chapter 21 for the address to be used in submitting all applications to the Agency <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

Electronic Submissions

EPA's Office of Pesticide Programs (OPP) is pursuing use of electronic data submission and review tools to improve the efficiency and effectiveness of its regulatory processes. These improvements would apply to information delivery, review, exchange and archiving functions. The approach is being implemented using current technology, considers the needs of data submitters and reviewers, and addresses legal requirements regarding both the pesticide program and information technology choices. More information can be found in the Agency's electronic submission guidance <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>.

Contacts for Additional Information

For additional information concerning a specific application for registration, contact the Branch Chief or Product Manager assigned to the active ingredient contained in your product. See Chapter 21 for contact information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

For questions concerning the status of a new product application for registration, please contact the Office of Pesticide Programs, Information Technology and Resources Management Division (ITRMD) Front End Processing Staff <https://epa.gov/node/50777/>.

For questions of a general nature that do not pertain to any specific pesticide or pertain to a new pesticide active ingredient for which an application has not been submitted, contact the appropriate Ombudsmen (listed in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>).

References Cited in Chapter 2

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

To find current Code of Federal Regulations citations, use the e-CFR <https://www.ecfr.gov>.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide Registration and Classification Procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 157 - Packaging Requirements for Pesticide and Devices
- Part 158 - Data Requirements for Registration
- Part 161 - Data Requirements for Registration
- Part 162 - State Registration of Pesticide Products

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> as amended by the Food Quality Protection Act of August 3, 1996

- Section 3 - Registration of pesticides
- Section 4 - Reregistration of pesticides

Pesticide Registration Notices (PR Notices) <https://epa.gov/node/63243/>

- PR Notice 11-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions> - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)
- PR Notice 96-2 <https://epa.gov/pesticide-registration/prn-96-2-changes-child-resistant-packaging-crp-testing-requirements> - Changes to Child-Resistant Packaging (CRP) Testing Requirements
- PR Notice 97-9 <https://epa.gov/pesticide-registration/prn-97-9-electronic-submission-child-resistant-packaging-test-data-all> - Electronic Submission of Child-Resistant Packaging Test Data for all Pesticides and Child-Resistant Testing of Prefilled, Nonrefillable Insecticide Bait Stations not Designed or Intended to be Opened or Activated in a Manner that Exposes the Contents to Human Contact
- PR Notice 98-1 <https://epa.gov/pesticide-registration/prn-98-1-self-certification-product-chemistry-data-attachments> - Self-Certification of Product Chemistry Data w/ Attachments

Label Review Manual <https://epa.gov/pesticide-registration/label-review-manual>

Test Guidelines for Pesticides and Toxic Substances <https://epa.gov/test-guidelines-pesticides-and-toxic-substances>

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

- Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>
- Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>
- Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>
- Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>
  - — Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>
  - — Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>
  - — Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>
  - — Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>
- Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>
  - — Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>
  - — Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
  - — Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 28, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.



An official website of the United States government

Pesticide Registration Manual: Chapter 3 – Additional Considerations for Biopesticide Products

In this chapter:

- Additional Considerations for Biopesticide Products
- Products Exempt from Registration
- Registration Package for Biochemical and Microbial Pesticides
- BPPD PRIA Review Phases
  - 21-day Content Screen
  - Preliminary Technical Screen
  - In-depth review of the data
- Regulation of Plant-Incorporated Protectants
- Pheromone Regulatory Relief
- Data Portion
- Small-Scale Field Test Notifications for Certain Genetically Modified Microbial Pesticides
  - Notification and Reporting Requirements
- Petition for Exemption from Notification Requirements
- Substitution of an EUP Application for a Notification
- Contacts for Additional Information
- References Cited in Chapter 3

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Additional Considerations for Biopesticide Products

Biopesticides are a type of pesticide derived from such natural materials as animals, plants, bacteria, and certain minerals. For example, canola oil and baking soda have pesticidal applications and are considered

biopesticides. Biopesticides fall into three major classes: **microbial pesticides, plant-incorporated protectants, and biochemical pesticides**.

A separate chapter on biopesticides is included in this manual because there are different requirements for biopesticides <https://epa.gov/pesticides/biopesticides> that need to be explained in detail. This chapter should be referred to in conjunction with Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>, "Registering a Pesticide Product."

Microbial pesticides are microorganisms that produce a pesticidal effect that are:

1. eukaryotic microorganisms including, but not limited to, protozoa, algae, and fungi;
2. prokaryotic microorganisms, including, but not limited to, bacteria; or
3. autonomous replicating microscopic elements, including, but not limited to, viruses.

Microbial pesticides can control many different kinds of pests, although each separate active ingredient is relatively specific for its target pest(s). For example, there are fungi that control certain weeds and other fungi that kill specific insects.

The most widely used microbial pesticides are subspecies and strains of *Bacillus thuringiensis*, or Bt. Each strain of this bacterium produces a different mix of proteins, and specifically kills one or a few related species of insect larvae. While some Bt strains control moth larvae found on plants, others are specific for larvae of flies and mosquitoes. The target insect species are determined by whether the particular Bt produces a protein that can bind to a larval gut receptor, thereby causing the insect larvae to starve.

Plant-Incorporated-Protectants (PIPs) are pesticidal substances that plants produce and the genetic material that has been added to the plant. For example, scientists can take the gene for the Bt pesticidal protein and introduce the gene into the plant's own genetic material. Then the plant, instead of the Bt bacterium, manufactures the substance that destroys the pest. EPA regulates the protein and its genetic material, but not the plant itself.

Biochemical pesticides are pesticidal substances that:

1. are naturally occurring chemicals or are synthetically derived equivalents;

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. **Additional Considerations for Biopesticide Products**
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>

2. have a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of synthetically derived biochemical pesticides, are equivalent to a naturally occurring chemical that has such a history; and
3. have a nontoxic mode of action to the target pest(s)

Biochemical pesticides include, but are not limited to:

1. semiochemicals (insect pheromones and kairomones),
2. natural plant and insect regulators,
3. naturally occurring repellents and attractants, and
4. enzymes.

Biochemical pesticides include substances, such as insect sex pheromones, which interfere with mating, as well as various scented plant extracts that attract insect pests to traps. Because it is sometimes difficult to determine whether a substance meets the criteria for classification as a biochemical pesticide, EPA has established the Biochemical Classification Committee to make such decisions. The chair of the Committee is Russell Jones <https://epa.gov/node/50763/>.

Products Exempt from Registration

EPA has determined that pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA (40 CFR 152.20(a)). In addition, pheromones and identical or substantially similar compounds labeled for use only in pheromone traps and pheromone traps in which those chemicals are the sole active ingredients are not subject to regulation under FIFRA (40 CFR 152.25(b)).

Note: The use of pheromones in traps in conjunction with conventional pesticides, or in other application methods (other than traps), is subject to regulation under FIFRA.

Minimum risk pesticides that meet certain criteria are a special class of pesticides that are not subject to federal registration requirements because their ingredients, both active and inert, are *demonstrably* safe for the intended use. They are exempt from federal registration under section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA does not review or register pesticides that satisfy the 25(b) criteria (PR Notice 2000-6) <https://epa.gov/node/63243/>, though registration is required by most states. Read more about products exempt from registration <https://epa.gov/node/64449/>.

---

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

Registration Package for Biochemical and Microbial Pesticides

The application categories described in Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product> apply to all applications for registration of conventional, biopesticide, and antimicrobial pesticide products. All applications for registration must include the data, information, forms, and fees and/or fee waiver or exemption requests as described in Chapter 2.

Biochemical and microbial pesticides are, however, subject to a different set of data requirements for registration than conventional chemicals, and are listed in Data Requirements for Registration 40 CFR Part 158:

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- Subpart U : Biochemical Pesticides 158.2000
- Subpart V : Microbial Pesticides 158.2100

EPA has published guidance for developing these data in the Biochemical Pesticides Test Guidelines, OPPTS Series 880 <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/series-880-biochemicals-test-guidelines> and the Microbial Pesticides Test Guidelines, OPPTS Series 885 <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/series-885-microbial-pesticide-test-guidelines>. Please also refer to Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product> of this manual for general information on submitting an application for registration, and to Chapter 12 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit> for additional information concerning experimental use permits.

Several helpful tips are available on the Web page for biopesticides, specifically the Biopesticide Registration Tools Web page <https://epa.gov/pesticide-registration/biopesticide-registration>, to aid applicants in preparing biopesticide submissions. Among these are:

1. how to avoid Confidential Statement of Formula or product chemistry issues with biopesticide submissions <https://epa.gov/pesticide-registration/tips-avoiding-confidential-statement-formula-or-product-chemistry-issues>, and
2. examples of BPPD internal application checklists <https://epa.gov/pesticide-registration/pesticide-registration-manual-biopesticide-application-checklists-documents> for amendment and registration application review.

Genetically modified microbial pesticides may be subject to additional (or fewer) data requirements or information requirements on a case-by-case basis, depending on the particular microorganism, the parent microorganism, the proposed use pattern, and the manner and extent to which the organism has been genetically modified.

Additional data requirements may include:

- information on the genetic engineering techniques used;
- the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene)
- information on the control region of the gene in question;
- a description of the new traits or characteristic that are intended to be expressed;
- tests to evaluate genetic stability and exchange; and/or
- selected Tier II environmental expression and toxicology tests.

BPPD PRIA Review Phases

The Biopesticides and Pollution Prevention Division (BPPD) has grouped its review of Pesticide Registration Improvement Extension Act (PRIA 3) actions into five phases.

- Phase I includes in–processing, specifically, documentation of receipt of the application in the Agency's tracking systems, the PRIA 21-day initial content screen (including review for consistency with PR Notice 11-3), follow up on 11-3 issues, and initiation of the PRIA 3 Preliminary Technical Screen.
- Phase II includes completion of the preliminary technical screen, any follow-up regarding deficiencies identified during the screen, and Federal Register announcements such as a notice of filing of a tolerance petition, when applicable.
- Phase III includes primary science reviews and, in some cases, drafts of a Biopesticide Regulatory Action Document (BRAD). Start dates for Phases II and III are the same, as these phases generally occur concurrently.
- Phase IV includes secondary science reviews, risk and benefit assessments, and where appropriate, preparation for a Scientific Advisory Panel (SAP) meeting.
- Phase V includes (where appropriate) SAP meeting, document development, Office of General Counsel and senior management review, sign-offs, logging the action out of the tracking system, and final Federal Register notices announcing the decision.

21-day Content Screen

When EPA receives the application and the applicable fee required by PRIA 3, the Agency will screen the application during a 21-day period to determine if it contains all required forms, labeling, and data formatted as described in the Agency's guidance (PR Notice 11-3), and documentation of fee payment. The fee payment documentation may include a request for a fee reduction or waiver or an exemption. Any deficiencies identified during the 21-day Content Screen and uncorrected by the applicant may lead to the Agency's rejection of the application and retention of 25% of the fee.

Preliminary Technical Screen

After the 21-day Content Screen, PRIA 3 requires that a Preliminary Technical Screen be conducted within 45 days after the PRIA start date for submissions with PRIA decision review timeframes $\leq$6 months and within 90 days for submissions with PRIA decision review timeframes > 6 months. The purpose of the preliminary technical screen is to determine if the pesticide registration application and accompanying information and data are:

1. accurate and complete;
2. consistent with proposed labeling and any tolerance or tolerance exemption, and
3. likely to result in the granting of the application.

If the application fails the technical screen and the deficiencies cannot be corrected by the applicant within 10 business days after receipt of the Agency's notification of failure, the Agency will reject the application.

AR0000416

In-depth review of the data

Once the submission clears the two screens, it is placed into in-depth science review. If during this in-depth review the Agency determines that there are data deficiencies, the applicant is notified in writing of the deficiencies per 40 CFR 152.105 and allowed 75 days to make the corrections or additions to complete the application. If after 75 days, the applicant has not responded or failed to complete the application, the Agency will terminate further action and treat the application as if withdrawn. In this case, the completed application will have to be resubmitted and treated as a new application. If the applicant believes that the deficiencies cannot be corrected within 75 days, it must notify the Agency within those 75 days of the date on which it expects to complete the application. For registration applications that fall under the Pesticide Registration Improvement Act (PRIA), the Agency has timeframes in which decisions need to be made on the applications. Application deficiencies may require that the timeframe be extended, and Chapter 5's section on Negotiated Due Date Extensions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees#negotiated> describes the process for extending due dates. The Phase at which a deficiency is identified influences the new due date proposed.

Regulation of Plant-Incorporated Protectants

Consistent with the Coordinated Framework for Regulation of Biotechnology issued by the U.S. Office of Science and Technology Policy in 1986 (51 FR 23302) genetically modified (GM) crops with pesticidal traits fall under the oversight of EPA, the U.S. Department of Agriculture, and the U.S. Food and Drug Administration.

EPA's oversight focuses on the pesticidal substance produced (e.g., Bt Cry proteins) and the genetic material necessary for its production in the plant (e.g., cry genes). EPA calls this unique class of biotechnology-based pesticides plant-incorporated protectants (PIPs) and describes procedures specific for PIPs in Procedures and Requirements for Plant-Incorporated Protectants (40 CFR Part 174). Read tips regarding experimental programs for PIPs <https://epa.gov/regulation-biotechnology-under-tsca-and-fifra/tips-plant-incorporated-protectant-pip-experimental>. Further guidance on small-scale field testing of PIPs and low-level presence in food is listed in PR Notice 2007-2 <https://epa.gov/pesticide-registration/prn-2007-2-guidance-small-scale-field-testing-and-low-level-presence-food>.

Pheromone Regulatory Relief

The Agency acknowledges that use of certain types of pheromone products presents lower risk than conventional pesticides, and also acknowledges the unique properties of these niche-type products regarding their inherently narrow host range. To promote the use of pheromone products, the Agency initiated a regulatory relief program that allows flexible confidential statements of formula for pheromone experimental use permits (EUPs) to allow for active ingredient adjustments during the course of experimentation. The Agency has also published generic tolerances and relaxed the acreage cut-off when an EUP is required. Refer to Chapter 12 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit> on EUPs.

EPA established the following special regulations as a result of the pheromone regulatory relief program:

- exemption from requirement of a tolerance for inert materials in polymeric matrix dispensers, 40 CFR 180.1122 (58 FR 64494);
- exemption from requirement of tolerance for pheromones in polymeric matrix dispensers, 40 CFR 180.1124 (59 FR 14759);
- EUP limit raised to 250 acres for pheromones in polymeric matrix dispensers (59 FR 3681);
- EUP limit raised to 250 acres for testing of nonfood-use broadcast pheromones (59 FR 34182);
- EUP acreage limit raised to 250 acres for straight-chained pheromones (sprayables) (60 FR 168);
- tolerance exemption for straight-chained lepidopteran pheromones (sprayables), 40 CFR 180.1153 (60 FR 45399); and
- exemption from requirement of a tolerance for inert polymers in sprayable formulations, 40 CFR 180.1162 (61 FR 6551).

Data Portion

The data portion of a registration amendment that requires product-specific data may include the following items, as applicable:

- acute toxicity data, especially if a change is proposed in the precautionary labeling or the signal word for the product, and if no previously submitted data can be cited or bridged;
- product chemistry data if the basic or alternate formulas are being changed substantially; and
- efficacy (product performance) data if proposing to add a new pest of public health significance, e.g., products to control pathogenic bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats, and mice. Changes to the basic product formulation may also require additional efficacy data.

Please note that efficacy data for nonpublic-health uses must be conducted and maintained on file by the registrant, although these data are not generally required to be submitted for review.

Important Note: When submitting data, three copies are required, properly bound and formatted in accordance with PR Notice 86-5 <https://epa.gov/node/51183/> Refer to Chapter 15 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential> for additional information on submitting data.

AR0000418

Small-Scale Field Test Notifications for Certain Genetically Modified Microbial Pesticides

Notification and Reporting Requirements

Applicants must submit a notification to EPA to obtain approval before starting small-scale testing of certain genetically modified microbial pesticides or non-indigenous microbial pesticides that USDA has not previously acted upon. This approval covers intentional introduction into the environment or small-scale testing in a facility that lacks adequate containment and inactivation controls (40 CFR 172.45).

The notification should be submitted to EPA for approval at least 90 days prior to the initiation of the proposed test (40 CFR 172.46).

Mail the Notification as described in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

EPA will review and evaluate each Notification as quickly as possible and will make a determination no later than 90 days after receipt of the complete Notification. However, under no circumstances shall the proposed test proceed until the submitter has received notice from EPA of its approval of such test.

Before making a final determination, the Agency may

- require additional information,
- approve the proposed test provided the submitter makes certain modifications,
- require an EUP, or
- disapprove the test.

Petition for Exemption from Notification Requirements

A petition for exemption from the notification requirements for a specific microbial pesticide or class of microbial pesticides may be submitted to the Biopesticides and Pollution Prevention Division. EPA will review and evaluate petitions as expeditiously as possible (no later than 180 days after the submission or 90 days after the last submission of additional information, whichever is later), and may request further information from the petitioner to assess the proposed exemption adequately. EPA will

- grant the petition and publish a notice of proposed rulemaking in the Federal Register for a 45-day comment period; or
- deny the petition and provide the petitioner with a written explanation of EPA's decision (40 CFR 172.52).

AR0000419

Substitution of an EUP Application for a Notification

In lieu of a Notification, an application for an EUP may be submitted to EPA for approval.

Contacts for Additional Information

For contact information, refer to the Organizational Charts in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> or to the Biopesticides Contacts Web page <https://epa.gov/node/50763/>.

References Cited in Chapter 3

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

Find Code of Federal Regulations citations in the e-CFR.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide Registration and Classification Procedures
- Part 158 - Data Requirements for Registration
- Part 172 – Experimental Use Permits
- Part 174 – Procedures and Requirements for Plant-Incorporated Protectants
- Part 180 – Tolerances and Exemptions for Pesticide Chemical Residues in Food

Harmonized Test Guidelines <https://epa.gov/test-guidelines-pesticides-and-toxic-substances>

- Series 880 - Biochemicals Test Guidelines - Final Guidelines
- Series 885 - Microbial Pesticide Test Guidelines

Pesticide Registration Notices <https://epa.gov/node/63243/> (PR Notices)

AR0000420

- PR Notice 86-5 - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)
- PR Notice 2007-2 - Guidance on Small-Scale Field Testing and Low-level Presence in Food of Plant-Incorporated Protectants (PIPs)
- PR Notice 2000-6 - Minimum Risk Pesticides Exempted under FIFRA Section 25(b) Clarification of Issues

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

AR0000424

An official website of the United States government

Pesticide Registration Manual: Chapter 4 – Additional Considerations for Antimicrobial Products

In this chapter:

- Introduction
- What Is an Antimicrobial Pesticide?
- Types of Antimicrobial Pesticides
- Unique Label Claims and Efficacy Test Protocols
- Applying for Registration
- Use Patterns
- Other Relevant Guidance Documents
- Contacts for Additional Information
- References Cited in Chapter 4

Introduction

Antimicrobial pesticides comprise a highly diverse group of pesticides that is distinctly different from conventional pesticides and biopesticides. Although they are subject to the same basic regulatory provisions of FIFRA as are conventional pesticides and biopesticides, antimicrobial pesticides are also specifically defined in FIFRA section 2(mm) and subject to additional registration requirements described in FIFRA section 3(h). In addition, antimicrobial pesticides are managed solely by the Antimicrobials Division (AD) of the Office of Pesticide Programs. This chapter provides additional guidance unique to antimicrobial pesticides that is not covered in the other chapters.

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

What Is an Antimicrobial Pesticide?

"Antimicrobial pesticide" is defined in section 2(mm) of FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> as a pesticide that is intended to:

- disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or
- protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and
- is exempt from or not subject to a tolerance…or a food additive regulation.

The following products are also antimicrobial pesticides:

- any other chemical sterilant products (other than liquid chemical sterilant products exempted under FIFRA section 2(u) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>),
- any other disinfectant products,
- any other industrial microbiocide products, and
- any other preservative products that are not excluded below.

The following products are NOT antimicrobial pesticides:

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. **Additional Considerations for Antimicrobial Products**
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- wood preservative or antifouling paint products for which a claim of pesticidal activity other than or in addition to antimicrobial activity is made [Note: In other words, wood preservative and antifoulant paint products that only have claims pertaining to microorganisms are antimicrobial pesticides, but the presence of additional claims such as insecticidal claims make the product a non-antimicrobial pesticide];
- agricultural fungicide products, and
- aquatic herbicide products.

The following products may qualify for exemption from FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>:

- treated articles exempted under 40 CFR 152.25(a).

In general, antimicrobial substances used on inanimate surfaces are subject to FIFRA, whereas antimicrobial substances used in or on living animals or humans are subject to the Federal Food, Drug, and Cosmetic Act <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> (e.g., human or animal drugs, antiseptics, liquid chemical sterilants used on medical devices, etc.). Some antimicrobial products are subject to both FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> and FFDCA <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> (i.e., dual jurisdiction products) because they involve direct or indirect food uses, or use on food contact surfaces (see Use Patterns section below for uses that may be subject to both FIFRA and FFDCA). Also refer to FDA's web site for a description of antimicrobial products that are subject to the FFDCA <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-antimicrobial-food-additives>.

Types of Antimicrobial Pesticides

Antimicrobial pesticide products are categorized as either "public health" or "non-public health," depending on the specific claims made on each product's labeling. Registrants of public health antimicrobial pesticide products must submit efficacy data to support their application for registration or amendments to add public health claims, whereas registrants of non-public health antimicrobial pesticide products are required to generate efficacy data but not submit those data, unless EPA requests that the data be submitted on a case-by-case basis.

Public health antimicrobial pesticide products are those products that bear a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including but not limited to, microorganisms infectious to man in any area of the inanimate environment. A product makes a public health claim if one or more of the following apply:

1. A claim is made for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals).
2. A claims is made for the pesticide product as a sterilant, disinfectant, virucide, sanitizer, or tuberculocide against microorganisms that are infectious or pathogenic to man.
3. A claim is made for the pesticide product as a fungicide against fungi infectious or pathogenic to man, or the product does not clearly state that it is intended for use only against non-public health fungi.
4. A claim is made for the pesticide product as a microbiological water purifier or microbial purification system.
5. A non-specific claim is made that the pesticide product will beneficially impact or affect public health at the site of use or in the environment in which applied, and:

    - The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health microorganism and there is no other functional purpose for the ingredient in the product; or

    - The pesticide product is similar in composition to a registered pesticide product that makes explicit antimicrobial public health claims.

Examples of the most common public health products include:

AR0000430

- **Sanitizer** – A substance, or mixture of substances, that reduces the bacterial population in the inanimate environment by significant numbers, (e.g., 3 log10 reduction) or more, but does not destroy or eliminate all bacteria. Sanitizers meeting Public Health Ordinances are used on food contact surfaces and are termed sanitizing rinses.
- **Disinfectant** – A substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment. EPA registers three types of disinfectants based on the type of efficacy data submitted: Limited, General (or Broad-spectrum), and Hospital.
    - **Limited** - A disinfectant that is effective against only a specific major group of microorganisms (such as gram-positive [e.g., Staphylococcus aureus] or gram-negative [e.g., Salmonella enterica] bacteria) is considered to be a limited disinfectant.
    - **General or Broad-spectrum** – A disinfectant that is effective against both gram-positive and gram-negative bacteria (Staphylococcus aureus and Salmonella enterica) is considered to be a general or broad spectrum disinfectant. General or broad spectrum disinfectants have a wide variety of uses in residential, commercial, institutional, and other sites.
    - **Hospital** - A disinfectant that is a general or broad-spectrum disinfectant and also is effective against the nosocomial bacterial pathogen Pseudomonas aeruginosa is a Hospital disinfectant. These disinfectants are generally for use in hospitals, clinics, dental offices, or other health care related facilities.
- **Sterilant** – A substance, or mixture of substances, that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses. These products are commonly used in hospitals, laboratories, pharmaceutical clean rooms, and similar environments where sterilization is necessary.
- **Fungicide** – A substance, or mixture of substances, that destroys fungi (including yeasts) and fungal spores pathogenic to man or other animals in the inanimate environment.
- **Microbiological water purifier** – Any unit, water treatment product or system that removes, kills or inactivates all types of disease-causing microorganisms from the water, including bacteria, viruses and protozoan cysts, so as to render the treated water safe for drinking.
- **Tuberculocide** – A substance, or mixture of substances, that destroys or irreversibly inactivates tubercule bacilli in the inanimate environment.
- **Virucide** – A substance, or mixture of substances, that destroys or irreversibly inactivates viruses in the inanimate environment.

EPA's web site contains a series of Disinfectant Technical Support Section (DIS/TSS) information sheets that describe the efficacy data guidelines for public health antimicrobial pesticides. See our science policy guidance <https://epa.gov/pesticide-registration/efficacy-requirements-antimicrobial-pesticides> to view this information.

Nonpublic-health antimicrobial pesticide products are those products that bear a label claim to control microorganisms of economic or aesthetic significance, where the presence of the microorganism would not normally lead to infection or disease in humans. Examples of non-public health claims would include, but are not limited to, algaecides, slimicides, preservatives and products for which a pesticidal claim with respect to odor sources is made.

Find out about determining if cleaning products are considered as pesticides under FIFRA <https://epa.gov/pesticide-registration/determining-if-cleaning-product-pesticide-under-fifra>.

Animal disease pathogen and zoonotic microorganism products include products that are intended to prevent, destroy, or control microorganisms that cause significant animal diseases and/or have the potential to infect humans. Before the Foot-and-mouth disease outbreak in Great Britain in 2001, EPA generally considered these products to be non-public health products that did not require the submission of efficacy data to support label claims. However, after that event, EPA became concerned about the significant health impacts that these diseases can have on animals (or in some cases on humans) and their substantial economic impacts. Subsequently, the Agency has been requiring that registrants submit efficacy data to support these claims. Applicants should consult the Agency for a current listing of organisms that meet these criteria (see the Organization of International Epizootics' listing <https://www.woah.org/en/what-we-do/animal-health-and-welfare/animal-diseases/>).

Unique Label Claims and Efficacy Test Protocols

A registrant who wishes to add a claim for any specific public health microorganism other than those actually included in the product's basic efficacy testing (e.g, *Salmonella enterica, Staphylococcus aureus*, and *Pseudomonas aeruginosa*), must submit efficacy testing for each such additional microorganism. For example, to add a claim for the human immunodeficiency virus 1 (HIV-1) to a hospital disinfectant, the registrant must perform and submit acceptable efficacy testing supporting any claims for its product against that specific virus.

Because efficacy test protocols may not exist or be validated for certain microorganisms, the registrant should consult with EPA prior to testing with new or amended protocols. In such cases, the registrant should submit the proposed test protocol to EPA for review and acceptance prior to the study being conducted. If EPA accepts the data from the new efficacy test protocol <https://epa.gov/pesticide-registration/antimicrobial-policy-and-guidance-documents> and approves the claim requested by the registrant, then EPA will post the new protocol on its Web site for other registrants to use. For example, efficacy test protocols for several specific pathogens such as Feline Calicivirus as a surrogate for norovirus, Bovine Viral Diarrhea virus as a surrogate for Hepatitis C, and duck Hepatitis B virus as a surrogate for human Hepatitis B virus are available. (Read more about efficacy test protocols by going to the Antimicrobial Web page <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration> and using the search feature to locate a specific test or organism.)

Applying for Registration

Before assembling an application for product registration or an amendment to a product registration, an applicant or registrant should first consider contacting the appropriate Product Team and/or requesting a pre-application meeting to discuss and confirm the data and labeling requirements that apply to that application. The applicant or registrant

AR0000432

may go to the Antimicrobial Contact List <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division> for the Product Team contacts and for guidance on requesting a pre-application meeting <https://epa.gov/pesticide-registration/guidance-pre-application-meetings-new-active-ingredients-major-new-uses-and>.

The application categories described in Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product> apply to all applications for registration of conventional, biopesticide, and antimicrobial pesticide products. Also, all applications for registration must include the data, information, forms, and fees or fee waiver requests as described in Chapter 2. However, for antimicrobial pesticide products, the following additional items may be needed as part of an application for registration:

- **Documentation of Pre-Submission Consultation**. If a pre-submission consultation has occurred, the applicant should submit written documentation describing the consultation and a copy of any Agency correspondence regarding that consultation.
- **Product Samples**. Samples of the product should NOT be submitted with an application. Product or ingredient samples may be required by the Agency for various purposes but will be requested separately.

Use Patterns

EPA's regulation "Data Requirements for Registration," which was issued in 1984 as 40 CFR Part 158, specifies the types of data and information generally required to make sound regulatory judgments under FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> for each pesticide proposed for experimental use, registration, amended registration, or reregistration with respect to a pesticide product's potential for causing unreasonable adverse effects. On October 26, 2007, EPA promulgated final rules establishing updated data requirements for conventional (72 FR 60934), biochemical, and microbial pesticides (72 FR 60988). On May 08, 2013 EPA promulgated the final rules <https://www.regulations.gov/document/epa-hq-opp-2008-0110-0111> (EPA-HQ-OPP-2008-0110-0111) to update the data requirements for antimicrobial pesticides. These final rules include the new Part 158W.

The use patterns in 158W, are based on similarity of use, purpose, pesticidal function and, in some cases, application practice. Applicants should consult the Agency's Antimicrobial Division Contact List <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division> to determine who to contact for questions pertaining to antimicrobial pesticide use patterns and/or for advice when a use site is not listed below.

1. **Agricultural Premises and Equipment** - This use pattern includes many indirect food uses with mostly indoor use sites:

    - farm and farm animal premises such as animal houses and pens (including milk houses), parlors, stalls, and barns;
    - transportation vehicles used to transport animals;
    - equipment such as forks, shovels, scrapers; halters, ropes, other restraining equipment; racks, mangers, feeders, waterers, troughs, and fountains; and
    - food-handling equipment such as milking equipment.

2. **Food Handling/Storage Establishments**, Premises, and Equipment - This use pattern also includes many indirect food uses due to the treatment of food contact surfaces and the resultant human exposures. All use sites are indoor and include:

    - food or feed processing plants;
    - eating establishments such as restaurants and cafeterias;
    - food storage or distribution facilities;
    - commercial transportation vehicles, shipping and storage containers;
    - food or feed stores and markets; and
    - vending machines.

3. **Commercial, Institutional and Industrial Premises, and Equipment** - This use pattern includes nonfood-contact areas of commercial sites. Typically, antimicrobial pesticides would be applied to ceilings, doors, doorknobs, fixtures, floors, light switches, stairs, walls, windows, and woodwork as part of routine cleaning practices. Included within this use pattern are school and daycare institutions. This use pattern includes both indoor and outdoor uses. Some of the uses have the potential for significant exposure due to the repetitive nature of certain exposures, and therefore may be considered as high human exposure.

4. **Residential and Public Access Premises** - This use pattern includes mostly nonfood areas, although it includes food-handling areas in homes. Some of the uses have the potential for significant exposure due to the repetitive nature of certain exposures and therefore may be considered as high human exposure. Most uses are indoor and include:

    - premises, contents, and equipment of homes, apartments, mobile homes, and shelters, including home-based daycare;
    - public areas, public buildings, and public rooms; and
    - commercial kennels, or living quarters of pets, zoo animals, race horses, or laboratory animals.

5. **Medical Premises and Equipment** - Medical waste is defined as any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production of biologicals including, but not limited to, culture and stocks, pathological wastes, human blood and blood products, and sharps. This use pattern is considered to be indoor nonfood. Some of the uses have the potential for repeated exposure and therefore may be considered as high human exposure. Use sites include:

   - hospital or medical environments such as clinics, dental offices, nursing homes, sick rooms, morgues, and veterinary clinics; and
   - non-critical medical equipment such as bedpans, basins, and furniture.

6. **Human Drinking Water Systems** - Human drinking water systems include any methods used to provide potable water from raw water supplies. This use pattern is considered to be high human exposure due to the potential for human exposures via drinking water, as well as dermal exposures to the treated water. Use sites include:

   - public water systems;
   - individual water systems;
   - emergency water systems;
   - water purifier units;
   - private water systems of individual homes, farms, institutions, camps, resorts, and industrial plants; and
   - emergency water systems for the public, campers, travelers, military, and fishermen.

   EPA does not set tolerances for these uses under FIFRA.

7. **Materials Preservatives** - Materials preservatives are antimicrobial chemicals added during industrial processes to prevent the growth of microorganisms. Examples of such uses include paints, coatings, adhesives, textiles, and paper. This use pattern includes food and nonfood, and mostly indoor uses.

   This category is further divided into (a) indoor food, (b) indoor nonfood, and (c) indoor/outdoor nonfood uses. Certain uses in category (b) may have high human exposure potential, such as finger paints, and plastic making. Products registered for papermaking must have indirect food additive clearances from the U.S. Food and Drug Administration. Products registered for plastic making (i.e., where the antimicrobial in the plastic will kill microorganisms on items stored in a plastic container) require tolerances or tolerance exemptions from EPA under section 408 of FFDCA since plastics may come into contact with food items. Products in category (c) include coatings, paints (applied film), and dispersions, which have potential for widespread use.

8. **Industrial Processes and Water Systems** - Certain antimicrobial chemicals, known as microbiocides, are used to control the growth of bacteria, fungi, and algae in water systems. There are two types of systems: "once-through" and "recirculating."

   - For "once-through" systems, the water is not re-used, and is therefore released into the aquatic environment or a wastewater treatment plant after a single cycle through the system. Once-through uses have the potential for significant environmental exposure when the treated water is released to the environment. Large volumes of water (as much as millions of gallons per minute) may be released directly to a river, estuary, or marine environment within minutes or hours of adding the antimicrobial to the system. In addition to the potential for environmental exposure after release, there is the potential for high human exposure via drinking water if the intake pipe for a drinking water treatment plant is downstream. Also, the water could be used in crop and/or livestock production thus providing for additional human exposure.

   - However, for many uses of water in industrial plants the treated water is re-used repeatedly within the system, "recirculating" in the system multiple times until released into the aquatic environment or a wastewater treatment plant. EPA has assumed that the releases are scheduled as the antimicrobial has been "used up." Given the lower frequency of release, resulting in lower volumes released to the environment, recirculating uses are likely to have less environmental exposure than once-through systems.

   For the purposes of determining data requirements for environmental fate and ecological effects, the industrial processes and water systems use pattern are subdivided. Because of the distinct differences between the once-through and recirculating water systems, the once-through water system are grouped with the other use patterns with potential for higher environmental exposures and the recirculating water system with those use patterns with the potential for lower environmental exposures.

9. **Antifouling coatings** - Antifoulants are coatings and paints applied to boat hulls and bottoms, crab and lobster pots, and underwater structures or equipment to control the growth of freshwater or marine fouling organisms. Antifoulant coatings have the potential for high environmental exposure, most particularly for marine (both freshwater and saltwater) environments.

   Also included within this use pattern is ballast water, that is, the water that is pumped in and out of ballast tanks as a ship's weight changes due to loading and unloading of cargo. Ballast water provides needed stability for safe operation of marine vessels. In recent years there have been significant concerns about transport of marine species from one marine environment to another in ballast water. When discharged into a new environment, the new species may become invasive and disrupt the native ecology. Ballast water treatments (such as adding an antimicrobial to the ballast water before discharge) are intended to prevent this. The Agency has reviewed few applications for ballast water treatments, presumably because treatment of ballast water to prevent the transfer of microorganisms from one marine environment to another is relatively new. Since ballast water treatments also have the potential for high exposure to the aquatic (both freshwater and seawater) environment, EPA has grouped the ballast water treatment pesticide chemicals with the antifoulant coating pesticide chemicals.

AR0000437

10. **Wood Preservatives** - Wood preservative products are those that claim to control wood degradation problems due to fungal rot or decay, sapstain, molds, or wood-destroying insects. This use pattern has the potential for high exposure for both humans and the environment with mostly outdoor use sites. Certain uses can be food uses. The types of wood and the products that can be manufactured with this treated wood are:

    - freshly cut logs or lumber;
    - seasoned building materials;
    - utility poles, fence posts, and rails,
    - structural members;
    - structures and dwellings;
    - transportation vehicles (truck beds and support structures);
    - crop containers;
    - lawn furniture and decks;
    - playground equipment;
    - garden/landscape timbers; and
    - log homes.

    While wood preservative treatment plant sites are regulated under the Resource Conservation and Recovery Act (RCRA) <https://epa.gov/laws-regulations/summary-resource-conservation-and-recovery-act>, the focus of environmental risk assessment under FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> is on the use of the treated wood. Exposure concerns for wood treatment products are many and varied. The nature and extent of these concerns depend primarily upon the types of wood items treated and their end-use locations. For example, pressure-treated wood may be intended specifically for use in salt or fresh water, for ground or soil contact, or for above-ground use. Sapstain-control products are for temporary treatment and are not intended for ground, soil, or aquatic contact.

11. **Swimming Pools** - Products in this use pattern are used to prevent/control the growth of bacteria or algae in the water systems of swimming pools, Jacuzzis and hot tubs. This use pattern is considered to be high human exposure. Under routine use little or no environmental exposure is expected, as the water in swimming pools, Jacuzzis, or hot tubs is considered to be separated from the natural environment. However, when draining is needed, depending on the volume of water and the location of the pool or hot tub, it is most likely that discharge would be down-the-drain to a wastewater treatment plant, to a storm drain that discharges to a stream, or directly to soil.

12. **Aquatic Areas** - Products in this use pattern are designed to control or kill slime-forming bacteria, fungi, or algae in lakes, ponds, streams, drainage ditches, and other bodies of water. In addition to the potential for environmental exposure, there is the potential for high human exposure via drinking water if the intake pipe for a drinking water treatment plant is in a lake or downstream, or through recreational activities such as swimming. Also, the water could be used in crop and/or livestock production thus providing for additional human exposure.

Other Relevant Guidance Documents

EPA's Web page for antimicrobial pesticides <https://epa.gov/pesticide-registration/antimicrobial-policy-and-guidance-documents> provides numerous guidance documents that address a wide range of science and policy issues. For example, EPA has issued many Pesticide Registration (PR) Notices <https://epa.gov/pesticide-registration/pesticide-registration-notices-year> since the 1970s that include guidance relevant to antimicrobials. Applicants and registrants should review these and other guidance documents available on the EPA Antimicrobials Web page before submitting an application for registration or amendment.

Contacts for Additional Information

For contact information, refer to the organizational charts in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> or the Antimicrobials Web page <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division>.

References Cited in Chapter 4

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the sources of these documents.

Code of Federal Regulation, Title 40

- Part 152 – Pesticide registration and classification procedures
- Part 158 – Data requirements for pesticides

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

AR0000439

- Section 2(mm)
- Section 2(u)

Federal Food, Drug and Cosmetic Act <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>

- Section 408 - Tolerances and Exemptions for Pesticide Chemical Residues

Resource Conservation and Recovery Act (RCRA) <https://epa.gov/laws-regulations/summary-resource-conservation-and-recovery-act>

Label Review Manual <https://epa.gov/pesticide-registration/label-review-manual>

40 CFR Part 158W Data Requirements for Antimicrobial Pesticides

Pesticide Registration Home <https://epa.gov/pesticide-registration>
About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>
Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>
Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>
Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>
Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>
— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>
— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>
— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>
— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>
Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>
— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>
— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JULY 11, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

MAIN MENU

Search EPA.gov

Pesticide Registration

CONTACT US <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration>

Pesticide Registration Manual: Chapter 5 – Registration Fees

In this chapter:

- Registration Fees
  - Background
- Actions that Require a Fee
  - New Active Ingredient
  - New Use (As Defined in 40 CFR 152.3)
  - Experimental Use Permit (As Defined in 40 CFR 172.2)
- Fee Determinations and Payments
  - Small Business Fee Waivers
  - Fee Exemptions
  - Minor Use Fee Waivers/Exemptions
- Initial Contents Screen
- Preliminary Technical Screen
- Withdrawn Applications
- Decision Review Periods (PRIA 3 Timeframes)
  - Negotiated Due Dates or Due Date Extensions
  - PRIA 3 "Cannot Grant" Determination
- Denials
- Annual Pesticide Registration Maintenance Fees
- Contacts for Additional Information
- References Cited in Chapter 5

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Registration Fees

Background

An amendment to FIFRA in 2004 created a registration service fee system for applications for specific pesticide registration, amended registration, and associated tolerance actions. This amendment, contained in the Consolidated Appropriations Act of 2004 (Pub. L. 108-199 (HR 2673)), established a new section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>. The goal is to create a more predictable evaluation process for affected pesticide decisions and couple the collection of individual fees with specific decision review periods. The provision specific to FIFRA is also known as the Pesticide Registration Improvement Act of 2003 (PRIA) <https://epa.gov/pria-fees>.

The registration service fee system was reauthorized by the Pesticide Registration Improvement Extension Act (PRIA 3) <https://epa.gov/pria-fees> until September 30, 2019 although the decision times or the timeframe or amount of time that the Agency has to make a decision under the system do not apply to applications received after September 30, 2017.

Regulatory actions are categorized first by type of chemical (i.e., conventional, antimicrobial, or biopesticide chemical product), and next by the type of action (e.g., new active ingredient (nonfood use), new food use, new registration of an old product, etc.). Under this system, each individual category corresponds to a certain registration service fee and decision review period.

The fees and decision review periods may change between fiscal years and fees are periodically increased as prescribed by statute. Applicants should refer to the most recent fee schedule available on the PRIA 3 Web <https://epa.gov/pria-fees> page prior to paying a fee.

The Pesticide Registration Improvement Extension Act can be reauthorized and revised by Congress at any time. Congress may amend provisions such as the fee categories, fees, and procedures at that time. Changes in policy and process may also occur. Applicants should refer to the Agency registration service fee and PRIA 3 Web page <https://epa.gov/pria-fees> for the most recent regulations, policy and guidance and to determine whether their application requires a fee and the applicable decision review period. Some of the key links are provided below:

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. **Registration Fees**
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- Fee tables <https://epa.gov/pria-fees/fy-2023-2024-fee-schedule-registration-applications>
- Fee category decision tree <https://epa.gov/node/45435/>
- Small business waivers <https://epa.gov/node/46523/>
- IR-4 exemptions <https://epa.gov/node/46547/>
- Fee reduction and refund formula <https://epa.gov/node/49547/>
- Paying fees <https://epa.gov/node/46913/>

Actions that Require a Fee

A fee or a waiver from paying the fee is required for the following types of actions (refer to Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product> for additional information):

- new active ingredients,
- new uses,
- new products,
- certain amendments,
- certain tolerances,
- certain inert ingredients,
- certain combination products,
- cancer reassessments and certain ecological/endangered species assessments,
- manufacturing use products (MUPs),
- experimental use permits (EUPs),
- human study protocols and completed studies that require review by the Human Studies Review Board,
- certain covered actions that require external review by the FIFRA Science Advisory Panel,
- Gold Seal letters,
- Exclusive use of data extension requests.

Actions **not** covered by fees include but are not limited to:

AR0000448

- the re-establishment of a time-limited tolerance;
- review of confirmatory data submitted in support of an already-issued registration (excluding efficacy data);
- Agency-initiated amendments (e.g., label amendments to comply with a reregistration eligibility decision);
- label amendments involving an advisory statement as described in Pesticide Registration Notice 95-2; SEARCH EPA ARCHIVE <https://archive.epa.gov/>
- label amendments that involve only changes specified in Pesticide Registration Notice 2005-1 <https://epa.gov/pesticide-registration/prn-2005-1-labeling-statements-products-used-adult-mosquito-control>
- submission of a sub-registrant/supplemental distributor label;
- Special Local Needs registrations submitted under FIFRA section 24(c) <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>;
- Emergency Exemption requests submitted under FIFRA section 18 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>;
- notifications as described in Pesticide Registration Notice 98-10 <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments>;
- Fast-track amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>;
- Minor formulation amendments as described in Pesticide Registration Notice 98-10 <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments>
- registrant responses to State Label Information Tracking System (SLITS) inquiries; and
- 6(a)(2) submissions.

If, upon initial review by the Agency of an application submitted as a non-PRIA 3 action, the Agency determines that the application is covered by PRIA 3, the Agency will inform the applicant and invoice or bill the applicant for the registration service fee. The fee is due upon submission of the PRIA 3 application. If the applicant submits a pesticide registration application without a fee and withdraws the application before paying the fee, the applicant will nonetheless owe 25% of the fee.

Under PRIA 3, there are 189 fee categories that have been grouped to reflect the three major types of pesticidal products - antimicrobial (A categories), biopesticide (B categories), and conventional active ingredients (R categories) - and the type of action as well as inert ingredients and miscellaneous actions. EPA has issued and will update as needed its interpretation of the fee categories in fee interpretation guidance <https://epa.gov/pria-fees>. Questions concerning whether a fee is required or the interpretation of a fee category should be referred to the Registering Division.

General definitions for the difference types of actions covered by PRIA 3 include:

New Active Ingredient

- An active ingredient that is not currently contained as an active ingredient in any registered pesticide product.

New Use (As Defined in 40 CFR 152.3)

- New use, when used with respect to a product containing a particular active ingredient, means:
  - any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of a tolerance regulation under section 408 of the Federal Food, Drug, and Cosmetic Act;
  - any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or
  - any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, of the active ingredient to man or other organisms.

Experimental Use Permit (As Defined in 40 CFR 172.2)

A permit authorized under FIFRA section 5 that allows applicants to develop data to support an anticipated registration application and may involve a pesticide not registered with the Agency, or a registered pesticide for a use not previously approved in the registration of the pesticide.

Pesticides under experimental use permits may not be sold or distributed other than through participants and, if sold or distributed through participants, may be used only at an application site of a cooperator and in accordance with the terms and conditions of the experimental use permit. Read more about EUPs in Chapter 12 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>.

Fee Determinations and Payments

Under section 33(b)(2)(D), the fee is due upon submission of the application and is either

- the fee prescribed by the fee category;
- a request for an exemption from registration service fees; or
- a portion of the fee with the remainder covered by a request for a fee waiver or reduction.

A reduction of 50% or 75% in the fee can be granted for a qualified small business. Applications from federal and state agencies and those solely associated with a tolerance petition submitted by IR-4 can be exempted from registration service fees. Fees may be reduced or exempted for minor uses. Applications with exemptions and waivers are discussed in subsequent sections of this chapter.

Section 33(b)(2)(F) directs the Agency to reject any application submitted without the required registration service fee. A portion of the fee, 25%, is non-refundable once an application is submitted per section 33(b)(2)(G), even if it is rejected. If any fee is unpaid 30 days after the fee is due, it shall be treated as a claim of the U.S. government subject to subchapter II of chapter 37 of title 31, United States Code.

To help applicants identify the appropriate fee and pay it in advance of submitting an application (pre-payment) or upon submission to EPA, the Fee Determination Decision Tree <https://epa.gov/pria-fees/pria-4-fee-determination-decision-tree> is available. Through a series of questions and answers, pesticide registration applicants are led to the appropriate fee category and fee.

A certification of payment should be the first page of the submission or application and precede a cover letter or fee waiver or reduction request to enable the Agency to match a payment with an application. Credit or debit card, PayPal, Dwolla or wire transfer payments (ACH) can be made using the Department of Treasury's pay.gov system, which provides an acknowledgement of payment. Credit card payments will only be accepted on amounts not greater than $24,999. PayPal or Dwolla payments will only be accepted on amounts not greater than $10,000. Wire transfer payments (ACH) will be accepted in any amount. Please note that checks will not be accepted after October 1, 2015.

Once the Agency receives an application covered by PRIA 3, the Agency assigns it a fee category and fee. If the Agency has not received the appropriate payment, the Agency invoices the applicant for the unpaid portion, typically within 48-72 hours of receipt of an application. During an in-depth review of the application, the Agency may determine that the application belongs to a different fee category and if fees are due, will invoice the applicant for any difference owed. The invoice will contain payment instructions. In the case of an overpayment, the Agency will provide a refund for the overpaid amount. If upon receiving an invoice, an applicant disagrees with the PRIA 3 fee category or amount, it should not pay the fee and contact the appropriate Registration Ombudsman <https://epa.gov/node/51787/> to discuss the situation. The phone number of the Registration Ombudsman will be included in the invoice.

Unless the applicant is requesting a fee waiver or exemption, the decision review period (i.e., the PRIA 3 timeframe) begins 21 days after receipt of the application and the fee. When a fee category is changed, the PRIA 3 timeframe will be recalculated.

Small Business Fee Waivers

Each request <https://epa.gov/node/46523/> must be submitted with supporting documentation and a certification. If more than one registration application is submitted at the same time, the supporting documentation should be submitted with each registration request.

The Agency will review the documentation provided by the applicant as well as other available information to determine if the applicant meets the applicable criteria for a fee waiver. The Agency will respond in writing to the applicant with the decision regarding the waiver. If the waiver is denied, the letter or invoice will include the amount to be paid and instructions for submitting payment. Should an applicant disagree with the Agency's decision on a fee waiver or reduction, the applicant should respond to the invoice with a written appeal including a rationale explaining why the original request should be granted or the Agency's decision should be reversed, following the instructions on the small business fee waiver Web pages. Once received by the Office of Pesticide Programs, the Agency will review the appeal and then call the applicant to explain the Agency's decision, followed by a confirmatory letter.

Waiver Decisions and Decision Review Times

- If no additional fees are required, the decision review period begins the earlier of
  - the date the Agency grants the small business fee waiver or
  - 60 days after submission of the application.
- If the Agency grants the small business request but additional fees are still due, the decision review period begin when the Agency receives certification of payment of the outstanding portion of the registration service fee.
- If the Agency denies the request for a small business fee waiver, the decision time review period begins when the Agency receives certification of payment of the registration service fee.
- If the fee is paid in full before the Agency completes its review of the fee waiver request, the fee waiver request will not be considered further.

CBI Claims

A business confidentiality claim covering part or all of the information in the application may be claimed at the time it is submitted to the Agency. Information on such claims may be found in Chapter 10 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements> and Chapter 15 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential> describes how to submit Confidential Business Information (CBI).

Fee Exemptions

Under FIFRA section 33(b)(7)(E), the Agency shall exempt an application from the registration service fee if it determines that the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Research Project Number 4 (IR-4) and that the exemption is in the public interest. Submission of the application and the request for the exemption are coordinated by IR-4. Guidance on IR-4 exemptions <https://epa.gov/node/46547/> is available and should be closely followed. Applications from agencies of the federal government or a state government are also exempt from registration service fees <https://epa.gov/node/46567/>.

The Agency will review the exemption request and confirm that the request meets the criteria in section 33 – specifically, whether the application is solely associated with an IR-4 tolerance petition and the exemption is in the public interest or, in the case of a federal or state government exemption, whether the applicant qualifies as a federal or state agency. It is the applicant's responsibility to establish that it is in fact a state agency under applicable state law. EPA will generally defer to the opinion of a state attorney general on matters of state law and whether an applicant is a "state agency." The decision time review period begins when the Agency grants the exemption from a registration service fee.

Minor Use Fee Waivers/Exemptions

Either a fee waiver or exemption may be requested with an application for a new minor use under FIFRA section 33(b)(7)(D). In general, the Agency may exempt the fee or waive a portion of the registration service fee for an application for minor uses of a pesticide. Applicants requesting such a waiver or exemption shall provide supporting documentation

that demonstrates to the satisfaction of the Agency that anticipated revenues from the uses that are the subject of the application would be insufficient to justify imposition of the full application fee. Applicants may also contract a Registration Ombudsman <https://epa.gov/node/51787/>.

The Agency will review a minor use exemption or partial fee waiver request to determine whether the use is a minor use and that anticipated revenues will be insufficient to justify imposition of the entire fee. In the case of a request for a minor use exemption, the decision review period begins when the Agency grants the exemption from a registration service fee. In the case of a request to waive a portion of the fee, the start of the decision review period will be calculated in the same manner as a small business waiver request.

Other Fee Reductions

Under section 33(b)(8)(C) of FIFRA, the Agency has discretionary authority to issue a partial refund (up to 75%) of registration service fee on the basis that, in reviewing the application, the Administrator has considered data submitted in support of another pesticide registration application or submitted in support of an application pending with the Agency on March 24, 2004. Some discretionary refunds are routine and are applied at the time of submission. Guidance on these refunds may be obtained on the primary/secondary <https://epa.gov/node/46487/> Web page and by contacting a Registration Ombudsman <https://epa.gov/node/51787/>.

All discretionary refund requests **must be requested** up front and be included in the application. Before submitting an application, it is recommended that discretionary refunds first be discussed with the appropriate Registration Ombudsman. In most instances, the applicant will pay the appropriate fee and the Agency will then provide the discretionary refund after the data have been reviewed and the Agency knows the amount of work involved. The request must be submitted either in the cover letter for the application or on the application form. The Agency suggests that the applicant as part of the request submit a rationale for the request. The rationale should reference the previous applications and could contain a comparison of the data submitted previously and with the application against the data requirements. To calculate the amount of any discretionary refund, the Agency will compare the data and information reviewed in past applications with that submitted in the new application. (For more information on refunds see **Fee reduction and refund formula** <https://epa.gov/node/49547/>). The maximum amount of any fee reduction is 75%. If a fee is reduced by 75% as a result of a discretionary refund, the fee cannot be further reduced by a small business fee waiver. A portion of the fee, 25%, is always nonrefundable. Also, if an application is rejected, a refund may be appropriate.

Initial Contents Screen

FIFRA section 33(f)(4)(B), “Initial Content and Preliminary Technical Screenings,” first directs the Agency, no later than 21 days after receiving an application and the required registration service fee, to conduct an initial screening of the contents of the application. In conducting this screen, the Agency must determine:

AR0000453

1. whether the applicable registration service fee has been paid; or
2. at least 25% of the applicable registration service fee has been paid and the application contains a waiver or refund request for the outstanding amount and documentation establishing the basis for the waiver request; and
3. that the application contains all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Agency.

A screening worksheet was developed and tested for the Agency's internal use and is available to help applicants assemble their submission. In conducting the screen, the Agency will verify that the payment requirements have been met. If they have not, the applicant must resolve any fee issue by the end of the 21-day period. The Agency will reject applications with an unpaid fee and invoice the applicant for 25% of the fee. If there are other missing contents, an Agency representative will contact the applicant with instructions on how to submit the missing form, label, data, or other information.

If the application fails the screen and cannot be corrected by the applicant within the 21-day period, the Agency will reject the application not later than 10 days after making the determination and will retain 25% of the fee.

Certain forms that are often missing from the data submission include the Offer to Pay statement, Formulator's Exemption statement, and the Data Matrix Form.

Specific problems with Data Matrix requirements include failure to include all required generic and product-specific data, and for data previously submitted to EPA, citing incorrect EPA Master Record Identifier (MRID) Numbers or the unique cataloging numbers assigned to individual pesticide studies at the time of their submission to EPA. The Certification with Respect to Citation of Data form (EPA Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) must always accompany a Data Matrix form.

An application will be rejected if the required three copies of the data are not properly bound and formatted.

Do not forget to provide a Data Matrix Form showing the data and for data previously submitted to EPA, corresponding MRID numbers if the Selective Method of data support is used. Applicants must use the Data Matrix to list companies to whom they have made offers to pay when using the Cite-all Method of data support.

After the 21-day initial content screen is completed, PRIA 3 directs the Agency to conduct a Preliminary Technical Screen of the application.

Preliminary Technical Screen

FIFRA section 33(f)(4)(B), "Initial Content and Preliminary Technical Screenings" directs the Agency to conduct a preliminary technical screen of the application. This screening is conducted no later than 45 days after the start of the decision review period for actions with decision review time periods equal to or less than 6 months and no later than 90 days after the start of the decision review period for actions with decision review time periods greater than 6 months. In conducting this technical screen, the Agency determines whether:

1. the application and the data and information submitted with the application are accurate and complete, and
2. the application, data and information are consistent with the proposed labeling and any proposed tolerance or tolerance exemption, and
3. the application, data and information are such that subject to full review could result in the granting of the application.

If the application fails the technical screen, and the deficiencies cannot be corrected by the applicant within 10 business days after receipt of the Agency's notification of the failure, the Agency will reject the application.

Withdrawn Applications

If the applicant withdraws a pesticide registration application before paying the fee, the applicant still owes the nonrefundable portion, 25%, of the fee. An invoice will be sent to the applicant for the amount due. Fees that are not been paid within 30 days of submission of the application are subject to collections.

If the applicant withdraws a pesticide registration application after paying a fee and during the first 60 days after the beginning of the applicable decision time review period, EPA must refund all but 25% of the total registration service fees. The Agency will confirm that the application has been withdrawn, and the refund will be sent to the applicant as soon as practical. However, if the applicant was granted a small business fee waiver of 75%, no refund will be provided since 25% of the fee is nonrefundable.

If a pesticide registration application is withdrawn after paying a fee and after the first 60 days after the beginning of the applicable decision time review period, EPA must determine what portion, if any, of the total registration service fee for the application may be refunded based on the proportion of the work completed at the time of withdrawal. The maximum that can be refunded is 75% of the total fee. The Agency uses a fee-reduction formula <https://epa.gov/pria-fees/overview-pria-fee-reduction-and-refund-formula>, updated for PRIA 3, and has 90 days to make this determination. The Agency will confirm that the application has been withdrawn and in this confirmation letter notify the applicant of the percentage of the fee that will be refunded. Any refund will be sent to the applicant as soon as practical. If the applicant was granted a small business fee waiver of 75%, no refund will be provided since 25% of the fee is nonrefundable.

Once an application has been withdrawn, any future submission related to the withdrawn application must be submitted as a new application that requires either the appropriate fee, a percentage of the fee with a fee waiver request for the remainder, or a request for an exemption of the registration service fee.

Decision Review Periods (PRIA 3 Timeframes)

Each PRIA 3 fee category has an associated period of time in which the Agency must make a determination, which has been called a decision review period or PRIA 3 timeframe. The Agency is committed to meeting the "PRIA 3 due dates." For applications that do not include a request for a waiver or exemption, the PRIA 3 timeframe begins 21 days after receipt of the application and fee. As previously described, for applications with a waiver or exemption request, the PRIA 3 timeframe begins when the request is granted, or in the case of a waiver request, if no additional fee is required,

the earlier of (i) the date the Agency grants the waiver or (ii) the date that is 60 days after receipt of the application. If the Agency denies the request for a waiver or if it grants the waiver and additional fees are required, the decision review period begins when the Agency receives payment of the outstanding portion of the registration service fee.

At any time after the 21-day initial content screen and the 45-day or 90-day preliminary technical screen, during the Agency's in-depth review of an application, the Agency may determine that an application is incomplete or that further information is needed in order to complete the Agency's review. A 75-day deficiency letter may be issued pursuant to 40 CFR 152.105 notifying the applicant that the applicant has 75 days in which to address the deficiencies or provide a schedule for addressing the deficiencies. If, after 75 days, the applicant has not responded, or fails to address the deficiencies within the time scheduled, the Agency will treat the application as if it has been withdrawn by the applicant. Once the Agency withdraws the application, a determination will be made on a refund as described in the section "Withdrawn Applications."

The Agency may also determine that there will be insufficient time for an applicant to submit the needed data/information and/or the Agency to review the data/information within the PRIA 3 timeframe. The Agency will then contact the applicant and discuss the situation. Some possible outcomes include:

- withdrawal of the application (and a determination with respect to any refund);
- negotiation of a new due date with the Agency;
- a determination by the Agency on whether the application, in the absence of the data, can be granted; or
- a denial of the application based on data (or lack thereof) before the Agency.

Negotiated Due Dates or Due Date Extensions

The PRIA 3 due date may be extended by a mutual agreement between the applicant and the Agency. The new due date is called a negotiated due date. Negotiated due dates occur predominately as a result of missing information or data or data deficiencies identified during an in-depth review of the application. The due date then is extended to allow the applicant the time to submit the data or information and for the Agency to review the data and make a determination.

In estimating the amount of time that may be required to address the issues and then make a determination on the application, the Agency analyzes which steps in its process need to be completed and the amount of time required for each. Steps in processing an application may include in-processing or intake of a submission, screening to determine its contents, data review, secondary or management review of documents, risk assessment, and regulatory decision-making. The amount of time that the applicant may take to submit the data or information is estimated and then the registering division estimates the amount of time it will take to reach a determination on the application.

Delays in submitting information may result in the applicant requesting additional extensions in the due date; however, additional delays in submitting the data or information may result in a determination that the Agency cannot grant the application or denial of the application. If substantial delays are expected in submitting the data or information or a new due date cannot be estimated by the applicant, the applicant is advised to withdraw the application and submit a new application with the data or information at a later date. The withdrawal procedures in the section "Withdrawn Applications" would apply.

The process for reaching a negotiated due date generally involves the applicant submitting its request for or consent to an extension in writing (e-mail is sufficient) to the Agency representative, generally a Product Manager or Regulatory Action Leader. The registering division then finalizes the agreement by obtaining the approval of the Office Director or Deputy Office Director.

PRIA 3 "Cannot Grant" Determination

A determination by the Agency that it cannot grant the application completes the Agency's review of the application under PRIA 3. Usually, it is a determination that on account of missing or deficient data, the Agency has determined that the application does not meet the standard for registration and, therefore, the application cannot be granted. It is not, however, a denial of the application pursuant to FIFRA section 3(c)(6). Once the Agency makes a determination that it cannot grant the application, the applicant may withdraw the application, continue to address any deficiencies without a PRIA 3 timeframe, or request a denial. If the applicant does not request the Agency to initiate denial proceedings or withdraw the application, the Agency may continue to diligently work with the applicant without a PRIA 3 timeframe or due date.

Denials

The denial process is described in section 3(c)(6) of FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>and 40 CFR Part 152 . The process includes publication of a notice of denial in the Federal Register and a possible public hearing.

Annual Pesticide Registration Maintenance Fees

All section 3 and section 24(c) registrations are subject to an annual maintenance fee described in FIFRA Section 4(i)(5) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>. PRIA 3 requires that $27.8 million in maintenance fees be collected for each of the five years of PRIA 3 (FY'13 – FY'17). Affected applicants will be contacted by mail in November with instructions for submitting the fee, which is due by January 15. No extensions of this due date are possible. The amount of the 2013 maintenance fee was $3,250 per product up to pre-set limits determined by legislation. The amount of the per product fee will vary from year to year as the fee is dependent upon the projected number of products for which registrants will pay this fee.

Although there are procedures for requesting a fee waiver for individual products, maintenance fees will be reduced by 25% for the first registration only, if the applicant can show that:

1. the applicant has 500 or fewer employees globally,
2. during the 3-year period prior to the most recent maintenance fee billing cycle the applicant has **average annual gross revenue** from all sources that do not exceed $10,000,000, and
3. the applicant holds a total of 5 or fewer registrations subject to the maintenance fee.

There also are maintenance fee waivers for products that meet certain narrow criteria in two categories: minor agricultural use products and public health pesticides. The procedure for requesting a fee waiver for individual products is described in the instructions.

Contacts for Additional Information

If an applicant has a question regarding the category in which a potential submission may fall, the applicant may contact one of the Registration Fee Ombudsmen (See Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>).

References Cited in Chapter 5

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 3 - Registration of Pesticides
- Section 18 - Exemption of Federal and State Agencies
- Section 24(c) - Authority of States
- Section 33 - Pesticide Registration Service Fees

Code of Federal Regulation, Title 21

- Part 152 - Pesticide Registration and Classification Procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 157 - Packaging Requirements for Pesticide and Devices
- Part 158 - Data Requirements for Registration
- Part 161 - Data Requirements for Registration of Antimicrobial Pesticides
- Part 162 - State Registration of Pesticide Products
- Part 172 - Experimental Use Permits
- Part 174 - Procedures and Requirements for Plant-Incorporated Protectants

Federal Register Notices

AR0000458

- Federal Register Notice:March 17, 2004 (Volume 69, Number 52) Pesticides; Fees and Decision Times for Registration Applications (PDF) <https://www.govinfo.gov/content/pkg/fr-2004-03-17/pdf/04-6001.pdf>(10 pp, 223 K, About PDF <https://epa.gov/home/pdf-files>)
- Federal Register Notice: June 2, 2005 (Volume 70, Number 105), [Page 32327-32335] Pesticides; Revised Fee Schedule for Registration Applications (PDF) <https://www.govinfo.gov/content/pkg/fr-2005-06-02/pdf/05-10998.pdf>(9 pp, 178 K, About PDF <https://epa.gov/home/pdf-files>)
- Federal Register Notice:October 30, 2007 (Volume 72, Number 209), [Page 61465-61477] Pesticides; Revised Fee Schedule for Registration Applications (PDF) <https://www.govinfo.gov/content/pkg/fr-2007-10-30/pdf/07-5381.pdf>(13 pp, 237 K, About PDF <https://epa.gov/home/pdf-files>)
- Federal Register Notice: August 5, 2008 (Volume 73, Number 151)Page 45438-45450] Pesticides; Revised Fee Schedule for Registration Applications (PDF) <https://www.govinfo.gov/content/pkg/fr-2008-08-05/pdf/e8-17936.pdf>(13 pp, 195 K, About PDF <https://epa.gov/home/pdf-files>)
- Federal Register Notice: August 11, 2010 (Volume 75, Number 154) Page 48672-48683) Pesticides; Revised Fee Schedule for Registration Applications <https://www.govinfo.gov/content/pkg/fr-2010-08-11/html/2010-19720.htm>
- Federal Register Notice: September 26, 2013 (Volume 78, Number 187) [Page 59347 – 59359] Pesticides: Revised Fee Schedule for Registration Applications <https://www.govinfo.gov/content/pkg/fr-2013-09-26/html/2013-23368.htm>

PR Notices

- PR Notice 86-5 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions> - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)
- PR Notice 95-2 - Notifications, Non-Notifications and Minor Formulation Amendments SEARCH EPA ARCHIVE <https://archive.epa.gov/>
- PR Notice 98-10 <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments> - Notifications, Non-Notifications and Minor Formulation Amendments

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

- Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>
- Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>
- — Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>
- — Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>
- — Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>
- — Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>
- Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>
- — Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>
- — Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
- — Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.



An official website of the United States government

Pesticide Registration Manual: Chapter 6 – Amending a Registered Pesticide Product

In this chapter:

- Amending a Registered Pesticide Product
  - Amendment Toolkit
- Amendments Requiring No Scientific Review of Data (Fast Track)
  - Labeling Change
  - Formula Change
- Amendments Requiring Product-Specific Data
- Administrative Portion of the Registration Amendment Package
- Data Portion of Registration Amendment Requiring Product-Specific Data
- Amendments Requiring Generic Data ("New Uses")
- Administrative Portion of the New Uses Amendment Package
- Data Portion of the Amendment Package
- Review of Identical/Substantially Similar and Fast Track Amendments
  - Applications That Qualify for Expedited Review
  - Applications That Do Not Qualify for Expedited Review
  - Active Ingredients from Unregistered Sources
  - Deletion of Use Patterns or Use Sites
- How to Submit an Amendment Application for Expedited Review
- Final Printed Labeling
- Contacts for Additional Information
- References Cited in Chapter 6

This chapter covers all aspects of amending a registered product including label changes, formulation changes, associated data requirements, and the forms that need to be submitted.

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Amending a Registered Pesticide Product

Almost all modifications to the composition, labeling, or packaging of a registered product must be submitted to EPA with an application for amended registration (EPA Form 8570-1, Application for Pesticide Registration/Amendment <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>).

Applications for amended registration must contain the information required by 40 CFR 152.50, as applicable to the change requested. While not all changes to current registrations require an application for amendment, if an application for amended registration is required, the application must be approved by the Agency before the modified product may be legally distributed or sold.

Amendments for certain minor changes may qualify as a "notification," which does not require approval before sale or distribution. These amendments are discussed in Chapter 7 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>. General guidance for notifications is PR Notice 98-10 <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments>.

Amendment Toolkit

Documents Necessary for Amendments Requiring an Application

Generally, one or more of the following items may be required when submitting an amendment to a product registration for EPA approval:

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. **Amending a Registered Pesticide Product**
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

AR0000467

- EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Application For Pesticide/Amendment** (with the box checked [X] for Amendment);
- EPA Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Certification with Respect to Citation of Data** (if applicable);
- EPA Form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Data Matrix** (if data are required);
- EPA Form 8570-4 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Confidential Statement of Formula** (if applicable);
- EPA Form 8570-27 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Formulator's Exemption Statement** (if applicable);
- Child-resistant packaging certification <https://epa.gov/pesticide-registration/child-resistant-packaging-pesticides> (if applicable);
- Submission of supporting data (if applicable); and
- Five copies of draft labeling (if applicable). Submitting labels electronically is highly encouraged. Submit a text PDF copy on a CD <https://epa.gov/pesticide-registration/electronic-submission-labels> and a Certification with Respect to Label Integrity <https://epa.gov/pesticide-registration/electronic-submission-labels> certifying that the text PDF copy is the same as the paper copy.

Amendments Requiring No Scientific Review of Data (Fast Track)

Fast track amendments include labeling changes or basic or alternate product formulation changes that do not require supporting data. Fast track amendments are also not subject to PRIA fees (for further information on PRIA fees, see Chapter 5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>).

If an amendment requests a change to a product that is "substantially similar" or "identical" to another product or "differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment" from another product, the similar or identical product and its applicable data may be cited instead of submitting required product-specific data. This amendment, now described as an "identical/substantially similar amendment," was formerly called a **"me-too" amendment**. Each applicant applying for an "identical/substantially similar" amendment must comply with the data compensation procedures as discussed in FIFRA section 3(c)(1)(F) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>. A discussion of these requirements and the applicable forms are in Chapter 10 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements> of this manual.

Fast track amendments require the following documentation:

Labeling Change

These amendments require an **Application for Pesticide Registration/Amendment** (EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>), and five copies of the proposed labeling. Labeling changes must comply with current regulations, policies, and format. Please refer to the Label Review Manual

AR0000468

<https://epa.gov/pesticide-registration/label-review-manual> for details regarding labeling changes. In addition, to facilitate processing, registrants are highly encouraged to submit their proposed label on a CD as a text PDF file <https://epa.gov/pesticide-registration/electronic-submission-labels> with a Certification with Respect to Label Integrity <https://epa.gov/pesticide-registration/electronic-submission-labels>.

Formula Change

Basic and alternate formula changes may be accomplished by amending a current registration only when the new formulation remains substantially similar to the original formula. See 40 CFR 152.43. An **Application for Pesticide Registration/Amendment** (EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, with the box checked [X] for Amendment); the **Confidential Statement of Formula** (EPA Form 8570-4 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>); and **Formulator's Exemption Statement** (if applicable) (EPA Form 8570-27 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) are required when a revision to the basic formulation or an alternate formula is requested. Five copies of draft labeling are required if the revision to the formula results in a change in the ingredient statement on the label and in addition, registrants are highly encouraged to submit their proposed label on a CD as a text PDF file <https://epa.gov/pesticide-registration/electronic-submission-labels> with a Certification with Respect to Label Integrity <https://epa.gov/pesticide-registration/electronic-submission-labels>.

Important Note: Some revisions to the formulation of pesticide products that control pests of public health significance may not be made through a fast track amendment. Such products (e.g., products to control pathogenic bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats, and mice), may require the submission of efficacy data to support the revised formulation.

Amendments Requiring Product-Specific Data

When a product is initially submitted for registration, data specific to the product are required to be submitted or cited (Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>).

If an amendment proposes to change a product's claims, precautions, or use directions such that the product or its labeling is substantially changed, then additional product-specific data may be required (e.g., acute toxicity, product chemistry, or efficacy) in some cases. Such amendments with product-specific data will require submission of an administrative package and a data package. Data previously submitted with another application may be cited instead. Any amendments that require data review are subject to PRIA fees (Chapter 5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>).

Important Note: The discussion provided below concerning the information to be submitted with a data-supported amendment is general in nature and does not cover all possible types of amendments. Questions about the type of information to be submitted with the application should be addressed to the appropriate Product Branch or Divisional Ombudsman <https://epa.gov/pesticide-contacts/contacting-epa-about-regulating-pesticides-issues>.

Administrative Portion of the Registration Amendment Package

The administrative portion of a registration amendment package includes the following:

AR0000469

- EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Application for Pesticide Registration/Amendment** (with box checked [X] for Amendment);
- For an "identical/substantially similar" amendment, a statement identifying the currently registered product that is "substantially similar" or "identical" or "differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment" by its EPA Registration Number and product name, and a description of the labeled change being proposed for the product;
- EPA Form 8570-4 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Confidential Statement of Formula**, if proposing a change in the formulation;
- EPA Form 8570-27 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Formulator's Exemption Statement**, if applicable;
- Five copies of the proposed draft labeling (Agency review is faster if the changes in the proposed labeling are:
  1. highlighted in a way that can be photocopied; or
  2. computer edited, with italics, shading, and strike-out; or
  3. hand marked on one copy; if a text PDF copy is submitted with a Certification with Respect to Label Integrity, the electronic label should not be marked up. The Agency will electronically compare the submitted label with the existing label to identify the proposed changes.
- EPA Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Certification with Respect to Citation of Data**; and
- EPA form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Data Matrix**. The data required to support the application may be addressed by either submitting the actual data or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix.

Data Portion of Registration Amendment Requiring Product-Specific Data

The data portion of a registration amendment that requires product-specific data may include the following items, as applicable (refer to 40 CFR 158 for data requirements and test guidelines for pesticides and toxic substances <https://epa.gov/test-guidelines-pesticides-and-toxic-substances> for testing protocols):

AR0000470

- Acute toxicity data (40 CFR 161.340, 40 CFR 158.500, 40 CFR 158.2050, and 40 CFR 158.2140); especially if a change is proposed in the precautionary labeling or the signal word for the product, and if no previously submitted data can be cited or referenced;
- Product chemistry data 40 CFR 161.150-190, 40 CFR 158.300-355, 40 CFR 158.2030, and 40 CFR 158.2120 if the basic or alternate formulas are being changed substantially; and
- Efficacy (product performance) data 40 CFR 161.640, 40 CFR 158.400, 40 CFR 158.2070, and 40 CFR 158.2160 if proposing to add a new pest of public health significance, e.g., products to control pathogenic bacteria, viruses, mosquitoes, ticks, roaches, fleas, rats, and mice. Changes to the basic product formulation may also require additional efficacy data.

Please note that efficacy data for nonpublic-health uses must be conducted and maintained on file by the registrant, although they are not generally required to be submitted for review.

Important Note: When submitting data, three copies are required, properly bound and formatted in accordance with PR Notice 86-5 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>. The Agency will at some point revise PR Notice 86-5 to reflect changes in process as a result of electronic submission. Applicants are advised to periodically consult the Agency's pesticides website <https://epa.gov/pesticides> or the Agency's registration ombudsman <https://epa.gov/pesticide-contacts/contacting-epa-about-regulating-pesticides-issues> for the latest guidance. Refer to Chapter 15 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential> for additional information on submitting data.

Amendments Requiring Generic Data ("New Uses")

An amendment that proposes to add a "new use" (i.e., a crop or site that is not currently registered for any product containing a particular active ingredient) must be supported by new data. Examples would be a new crop or animal feed use, or a change in use pattern from indoor to outdoor use. New uses are defined in 40 CFR 152.3. Supporting data for a new active ingredient and a new use are called generic data because they support the registration of the active ingredient rather than a specific product. Applications to amend a registration to add a new use contain an administrative portion and a data portion.

Important Note: The discussion provided below concerning the information to be submitted with a new use amendment is general in nature and does not cover all possible types of new use amendments. Any questions concerning what information should be submitted with an application should be directed to the appropriate Product Branch for the product in the Antimicrobials Division <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division>, Biopesticides and Pollution Prevention Division <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-biopesticides-and-pollution-prevention> or Registration Division <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-registration-division> (chemical pesticides).

Administrative Portion of the New Uses Amendment Package

The administrative portion of amendment applications includes the following:

- EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Application for Pesticide Registration/Amendment** (with the box checked [X] for Amendment);
- Five copies of the proposed draft labeling. (In addition, applicants should submit one label clearly marked to show the addition(s), deletion(s), or change(s) proposed for the amended labeling. This marked up label can be done on a copy of the proposed label or on the label that was previously registered.
- EPA's review is faster if the changes in the proposed labeling are:
  1. highlighted in a way that can be photocopied;
  2. computer edited with italics, shading, and strike-out; or
  3. hand marked; if a text PDF copy is submitted with a Certification with Respect to Label Integrity, the electronic label should not be marked up.
- EPA Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Certification with Respect to Citation of Data**;
- EPA Form 8570-27 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Formulator's Exemption Statement** (if applicable); and
- EPA Form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, **Data Matrix**. The data required to support the application may be addressed by either submitting the actual data or by referencing EPA's Master Record Identification (MRID) number on the Data Matrix Chart.

Data Portion of the Amendment Package

Applicants should refer to 40 CFR Part 158, and Test Guidelines for Pesticides and Toxic Substances <https://epa.gov/test-guidelines-pesticides-and-toxic-substances> to determine what data are required to support a new use. Applicants may be required to submit data on both the technical grade of the active ingredient and on the formulated product.

- In addition, new food or feed uses will require a petition for a tolerance or an exemption from the requirement of a tolerance. Please refer to Chapter 11 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions> for a discussion on Tolerance Petitions.

Review of Identical/Substantially Similar and Fast Track Amendments

Section 3(c)(3)(B)(ii) of FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> requires EPA to expedite (fast track) the review of certain applications including amendments of a registered product for which scientific review of the data is not required. This section deals with fast track amendments that require no scientific data review by the Agency.

For these amendments, EPA is required to:

- determine within 21 days of receipt whether or not the application contains all of the necessary forms and labeling formatted in accordance with guidance published by the Agency and, if determined that contents are missing, to reject the application;
- notify the applicant within 90 days after receiving a complete application whether the application has been granted or denied; and
- notify the applicant in writing of the specific reasons if the application is denied.

Applications That Qualify for Expedited Review

Applications for amended registration that do not need scientific review qualify for expedited registration under FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> section 3(c)(3)(B)(ii). This includes any labeling or formulation change that is not significant (i.e., does not significantly increase risk) and for which either no data or minimal (i.e., confirmatory product chemistry, acute toxicity, or efficacy) data are submitted (for example, one or two acute toxicity bridging studies).

Applications That Do Not Qualify for Expedited Review

EPA will not expedite applications to amend the registration of products for which the proposed formulation or labeling varies significantly from that of currently registered products. Applications will not be expedited if the proposed amendments:

- change the product so that it is not “substantially similar” or “identical” to another EPA registered product, or
- substantially change the same product, or
- require review of scientific data.

Active Ingredients from Unregistered Sources

EPA will not expedite applications to amend the registration of products proposing unregistered source(s) of the active ingredient because extensive product chemistry and often toxicology data are required for these types of amendments. These data are more complex and require more time to review than the data associated with the administrative

AR0000473

applications for an amended registration described above. These applications are subject to PRIA <https://epa.gov/pria-fees> and have an associated fee <https://epa.gov/pria-fees>.

Deletion of Use Patterns or Use Sites

EPA will not expedite applications to amend the labeling of a registered product to delete use patterns and sites of use. Amendments for use deletions must be accompanied by a request for voluntary cancellation as described in section 6(f) of FIFRA. FIFRA requires the Agency to publish 6(f) requests in the *Federal Register* and provide an opportunity for public comment on the requested use deletion before EPA may act upon such a request. Read about the voluntary cancellation process <https://epa.gov/node/189017>.

How to Submit an Amendment Application for Expedited Review

When submitting an application for amended registration to qualify for expedited "fast track" review, the word **"EXPEDITE"** (typed or printed) should appear at the top of the Application for **Pesticide Registration/Amendment** ((EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) with the box checked [X] for Amendment) to facilitate identifying the application for expedited review.

If the application is a submission of additional information in response to an objection letter from EPA, the word **"EXPEDITE-RESUBMISSION"** (typed or printed) should appear at the top of the **Application for Pesticide Registration/Amendment** (EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) with the box checked [X] for Amendment) and must include a copy of EPA's objection letter to allow the Agency to efficiently process the application.

Important Note: For an explanation of the review process and procedures for processing applications, refer to Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>.

Final Printed Labeling

After acceptance of a new product registration, labeling amendment, or labeling notification, final printed labeling must be submitted before the product is sold or distributed. See 40 CFR 156.10(a)(6). Two copies of the final printed labeling that incorporate any labeling changes required by the acceptance letter and/or notification must be submitted.

Contacts for Additional Information

Any questions or need for additional information regarding label amendments should be directed to the appropriate Product Manager/Team Leader assigned the product in question. Refer to Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> for a listing of Product Branches. Please contact the Product Manager if there are questions concerning the status of identical/substantially similar or "me too" product applications.

References Cited in Chapter 6

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide Registration and Classification Procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 157 - Packaging Requirements for Pesticide and Devices
- Part 158 - Data Requirements for Registration
- Part 158W - Data Requirements for Antimicrobial Pesticides
- Part 180 - Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Foods

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 2 - Definitions
- Section 3 - Registration of pesticides
- Section 6 - Administrative review; suspensions
- Section 12 - Unlawful Acts

Pesticide Registration Notices Web Site <https://epa.gov/pesticide-registration/pesticide-registration-notices-year>

Label Review Manual <https://epa.gov/pesticide-registration/label-review-manual>

Pesticide Registration Home <https://epa.gov/pesticide-registration>
About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>
Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>
Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>
Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>
Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>
— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>
— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>
— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

MAIN MENU

Search EPA.gov

Pesticide Registration

CONTACT US <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration>

Pesticide Registration Manual: Chapter 7 – Notifications and Minor Formulation Amendments

In this chapter:

- Notifications, Non-Notifications, and Minor Formulation Amendments
  - Parties Authorized to Submit
- Labeling Notifications
  - Permitted Modifications to Registrations through Notification
- Product Chemistry Notifications
- Submitting Notifications
- Non-Notifications
- Minor Formulation Amendments
  - Criteria for Accelerated Review
  - Grounds for Denying Accelerated Review
  - Submitting Minor Formulation Amendments
- Final Printed Labeling
- Contacts for Additional Information
- References Cited in Chapter 7

Notifications, Non-Notifications, and Minor Formulation Amendments

This chapter discusses certain minor amendments that can be made to a registered product and do not require the applicant to apply to amend a registration. Such amendments are not subject to the data compensation provisions of FIFRA section 3(c)(1)(F) <https://epa.gov/laws-regulations/summary-

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

federal-insecticide-fungicide-and-rodenticide-act> because they do not need to be supported by new data. To emphasize that these applications can only be submitted by the registrant of the product, the applicant is generally referred to as "the registrant" in this chapter.

Some minor changes referred to as "notifications" can be made to a registration, such as changes to a brand name, provided that the Agency is notified before the change is made and before the product is distributed or sold.

"Non-notifications" are changes that can be made to a pesticide label without notifying the Agency (such as the correction of typographical errors).

Although a formulation change may only be accomplished through applying for amended registration, the Agency has developed an accelerated review process for certain "minor formulation amendments" (such as the addition, deletion, or substitution of one or more fragrances, colorants, or other inert ingredients in a formulation).

A notification does not constitute official acceptance of the product label, nor does it guarantee the product's compliance with regulations. For more detailed information, please refer to PR Notice 98-10 Notifications, Non-Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments>.

Parties Authorized to Submit

Only the registrant or the authorized agent for the company may submit a notification or minor formulation amendment, which must be properly signed and dated. The registrant is also responsible for ensuring that the labeling of any of its distributors or supplementally registered products is in compliance with FIFRA. (Refer to 40 CFR Part 156) Supplemental distributors, commonly known as sub-registrants, may not submit notifications, nor may registrants submit supplemental distributor labeling for notifications.

Important Note: An applicant or registrant should be aware that knowingly falsifying any part of any application for registration or other information submitted to the Agency is an unlawful act under FIFRA section 12 (a)(2)(M) and 18 USC 1001 and may result in civil or criminal penalties.

Labeling Notifications

Certain permitted changes to a registration require a notice to EPA but do not require Agency approval. As provided in 40 CFR 152.46(a), minor changes that the Agency has determined have no potential to cause

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. **Notifications and Minor Formulation Amendments**
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>

unreasonable adverse effects to the environment can be made to a registration, provided that the Agency is notified before the change is made. OPP refers to these changes as “notifications.” As described in 40 CFR 152.46(a), the Agency has issued a notice describing which actions are appropriate as notifications and the procedures to follow. See PR Notice 98-10 <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments>.

Except for the special procedures for antimicrobials discussed below, it is not necessary to obtain Agency approval of such a change or amendment, and the product may be distributed or sold, as changed, as soon as EPA receives the notification of the change, as long as EPA does not reject the notification. However, to assure the registrants and state regulatory agencies that a notification has been received and reviewed by the Agency, the Agency is attempting to respond in writing to all notifications.

FIFRA, as amended in 1996, specifies slightly different notification requirements for antimicrobial products (FIFRA section 3(c)(9)). For antimicrobial products, registrants must notify the Agency of certain labeling changes at least 60 days prior to distribution or sale of a product bearing the new label. The Agency may disapprove changes within 30 days of their receipt.

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

> - For any requested change made through notification, the Agency reserves the right to require that a formal application for amended registration be submitted.

Normally, EPA will screen a notification within 30 days of receipt. If EPA determines that the proposed amendment (change) does not qualify as a notification, the Agency will notify the applicant, stating the reason(s) why an application is required for amended registration in lieu of a notification. If the registrant fails to submit an application for amended registration without good cause, and markets the product as if the notification was accepted, the Agency may determine that the registered product is no longer in compliance with the requirements of FIFRA and initiate regulatory action under FIFRA section 6 and/or enforcement actions under FIFRA section 13 <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> and section 12 <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>.

Permitted Modifications to Registrations through Notification

EPA issued general procedures for notifications in PR Notice 98-10 <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments> and a list of changes that may be made through notification. Subsequent PR Notices have modified the original list. As described in PR Notice 98-10, the following registration amendments generally may be accomplished by notification. See PR Notice 98-10 for more descriptions on these categories.

- Brand Names
- Addition or Deletion of Pests on the Label
    - Exceptions: To add claims to a label against a public health pest, termites, or pests on plants subject to quarantine, the registrant may not use notification, but must receive approval to amend the pesticide product registration. Public health pests include, but are not limited to, mosquitoes, cockroaches, fleas, ticks, biting flies, rodents, viruses, and pathogenic bacteria. Refer to PR Notice 2002-1 for list of public health pests <https://epa.gov/pesticide-registration/prn-2002-1-lists-pests-significant-public-health-importance>. Special instructions to add claims for H1N1 can be found on the Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu) web page. SEARCH EPA ARCHIVE <https://archive.epa.gov/> Questions about public health pests, termiticides, and products used for plant quarantine may be referred to the appropriate regulatory division <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-regulatory-divisions-ad-bppd-prd-rd> that manages those products.
- Addition of Indoor, Nonfood Sites for Antimicrobial Products
- Changes in Packaging and Related Labeling Statements (except Child Resistant Packaging)
- Use Deletions Related to a Data Call-In

AR0000484

- Storage and Disposal Statements
  - Registrants may adopt storage and disposal labeling statements as specified in the following notices without submitting an amendment for approval:
    - PR Notice 83-3 <https://epa.gov/pesticide-registration/prn-83-3-label-improvement-program-storage-and-disposal-label-statements> Label Improvement Program – Storage and Disposal
    - PR Notice 84-1 <https://epa.gov/pesticide-registration/prn-84-1-clarification-label-improvement-program-farmworker-safety-and> Clarification of Label Improvement Program
  - Since PR Notice 98-10, the storage and disposal statements have been revised according to the following PR Notices.
    - PR Notice 2007-1 <https://epa.gov/pesticide-registration/prn-2007-1-disposal-instructions-non-antimicrobial-residential-or-household> Disposal Instructions on Non-Antimicrobial Residential or Household Use Pesticide Product Labels
    - PR Notice 2007-4 <https://epa.gov/pesticide-registration/prn-2007-4-labeling-revisions-required-final-rule-pesticide-management-and> Labeling Revisions Required by the Final Rule “Pesticide Management and Disposal Standards for Pesticide Containers and Containment"
  - Registrants may continue to adopt labeling statements verbatim from these notices by notification. However, a request for variation in the wording of these statements must be submitted as an amendment.
- Use of Symbols and Graphics
- Redundant Labeling Statements
- Changes in Warranty Statement
- Labeling Statements about Product Composition (such as pesticide category, source of ingredient(s), odor or fragrance statements, and water-based statements)
- Risk Reduction Statements (such as non flammability or closed system statements)
- Minor Changes to Directions for Use (such as changes in mixing directions that do not affect the dilution ratio or the minimum or maximum use dilutions; addition of tables, charts, or other graphics; addition of similar application methods; and mixing with a fertilizer).

Other Allowable Minor Label Revisions

There are additional minor label changes not described above that may be made by notification, provided they:

> - are consistent with or specified by a PR Notice <https://epa.gov/pesticide-registration/pesticide-registration-notices-year>; or
> - are consistent with 40 CFR Part 156; and
> - involve no change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use.

Product Chemistry Notifications

See PR Notice 98-10 for more descriptions on these categories.

Source of Active Ingredients

A registrant may change the source of an active ingredient by notification, provided that the alternate source:

- is registered for at least the same uses for which the formulated product is registered; and
- is similar to the current source, i.e., meets the criteria given in 40 CFR 152.43(b)(1) and (2))

A registrant must submit a Formulator's Exemption (EPA Form 8570-27) <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms> along with the notification of source change if the new source is registered for the same uses as the existing source (40 CFR 152.85(c)).

Changes to Active Ingredients That Are Not Allowed by Notification

A registrant may **not** make the following active ingredient related changes by notification but must submit an application for amendment:

- A change in the source of an active ingredient that would result in a change in a nominal inert ingredient total or result in a changed toxicological category or chemical property of a product. This changed formula would be considered an alternate formulation.
- A change to an unregistered source of an active ingredient.
- Addition, deletion, or substitution of an active ingredient, or increase or decrease in the amounts of existing active ingredients. This would constitute a new formulation, which may require a separate registration.
- A change in the stated nominal concentration of any active ingredient or change of certified limits from that shown on the previously submitted Confidential Statement of Formula (CSF), EPA Form 8570-4 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>.
- A new source that is not registered for the complete set of uses as the existing source. An amendment for registration and a FIFRA 6(f) request must be submitted to delete unsupported uses from the formulated product, or an amendment for registration citing or providing appropriate data to support the additional uses must be submitted.

Change in Source of Inert Ingredients

If the Agency has required that a registrant identify the source of an individual inert ingredient, the identity of which is known to the registrant, the registrant may change the source of that inert ingredient by notification.

AR0000486

- If EPA has not required identification of the source of an inert ingredient, the registrant may change a source without notification to the Agency.

Change in Nominal Concentration of Inert Ingredients

A registrant may change the stated nominal concentration of any inert ingredient by notification, provided that:

- the nominal concentration falls within the certified limits for that ingredient as listed on the accepted CSF; and
- the composition of the ingredient is known to the registrant.

Change in the Certified Limits of Inert Ingredients

A registrant may change the certified limits of any inert ingredient(s) in a formulation by notification, provided that they fall within the standard certified limits in 40 CFR 158.350 for 40 CFR 161.175 for antimicrobials.

Changes to Inert Ingredients Not Permitted by Notification

EPA does **not** permit changing proprietary ingredients such as specific solvents or common commodity diluents by notification because they are generally composed of a mixture of ingredients and the registrant does not disclose their composition. Such changes would require the Agency to determine their acceptability based upon information on their composition supplied by the producer.

The Agency also does not permit changing inert ingredients by notification for:

- antifoulant paints (because such changes may affect the release rate of these products);
- products used for the control of vertebrate animals (because odor, taste and dye are usually crucial to product effectiveness); and
- baits used to control insects and vertebrates.

Certified limits of inert ingredients may not be changed via notification for products for which:

- the Agency has previously determined that alternative certified limits will apply; or
- the registrant has already changed the nominal concentration consistent with the requirements for changes in nominal concentrations of inert ingredients as listed in 40 CFR 158.350 and for antimicrobials, in 40 CFR 161.175.

Sources for Starting Materials for Integrated Systems Products

An integrated system is a process for producing a pesticide product that: (1) contains any active ingredient derived from a source that is not an EPA-registered product; or (2) contains any active ingredient that was produced or acquired in a manner that does not permit its inspection by the Agency under FIFRA section 9(a) before its use in the process. Refer to 40 CFR 158.300 and for antimicrobials, 40 CFR 161.153.

A registrant who produces a product by an integrated system and uses an unregistered source of active ingredient is required to supply the Agency with the sources of the starting materials for each ingredient. (40 CFR 158.325 and for antimicrobials, 40 CFR 161.160).

Registrants may change the source of the starting materials to other sources by notification if the integrated system product is:

- not a microbial pesticide, a botanical pesticide, or any other pesticide produced via any methods other than man-made chemical synthesis; and
- the change will not result in:
  - an increase in the upper certified limit of any existing impurity,
  - the formation of any new impurity at a level greater than 0.1 percent by weight of the technical grade active ingredient, or
  - the formation of other impurities of toxicological significance (e.g., dioxins, furans, nitrosamines, arsenicals) that have not previously been reported to, or that occur above levels previously permitted by, the Agency.

Changes to the Formulation Process for Non-Integrated Systems

A registrant may modify a formulation process of a product made by a non-integrated system (a blending or dilution of product components involving no chemical reaction-distinguished from a reaction process), provided:

- the certified limits of the active and inert ingredients do not change as a result; and
- the physical/chemical/biological characteristics or the effectiveness (efficacy) of the product will not change.

Submitting Notifications

Application Form: For each product, a notification should be submitted with a completed Application for Registration (EPA Form 8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>). A photocopy of the EPA application form is acceptable; an original form is not needed. In order for the application to be processed, include the following statements on the application:

AR0000488

> **"Notification of (insert type of change, such as 'Alternate Brand Name') per PR Notice 98-10"**
>
> "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Labeling: For each notification involving labeling changes, one copy of the labeling must be submitted with the changes clearly marked so that they can be photocopied.

Confidential Statement of Formula (CSF): Two original and signed CSFs must be submitted for either a notification or an amendment involving a CSF change. In addition, a Formulator's Exemption form (EPA Form 8570-27 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) must be submitted for any change in the identity or source of active ingredients.

Signature: Each notification must be signed by the registrant or authorized agent and include that person's current address and telephone number.

Address: Notifications should be sent to the address listed in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

Non-Notifications

In accordance with 40 CFR 152.46(b) and PR Notice 98-10 <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments>, a registrant may make certain changes to its pesticide label without notifying the Agency. See PR Notice 98-10 for more descriptions on these categories.

- Typographical and Printing Errors
- Changes in Package Size and Net Contents
- Revision, Addition, or Deletion of Non-FIFRA Related Label Elements
- Transfer of Ownership
- Changes in the Name or Address of the Registrant on the Label
- Redesign of Label Format

AR0000489

- Nonpesticidal Characteristics
  - The following are examples of nonpesticidal characteristics statement changes allowed by non-notifications:
    - Nonpesticidal Effectiveness;
    - Cleanup or Ease of Removal;
    - Effects on Treated Objects or Sites;
    - Price or Price-Related Marketing;
    - Where a Product Is Made;
    - Approval by Other Federal Agencies;
    - Consumer Access Numbers; and
    - Use of the Words “Other Ingredients” in the Ingredients Statement.

Statement of Practical Treatment

The heading “First Aid” may be substituted for “Statement of Practical Treatment” without notification to the Agency.

Product Packaging

The Agency allows the addition of “Recycled Content” claims to the pesticide label without prior notification. A statement about the recycled content of pesticide packaging itself may be made in accordance with guidance from the Federal Trade Commission.

Bilingual Labeling

A registrant may provide bilingual labeling on any product without notification to the Agency. EPA may require bilingual language as well. Refer to 40 CFR 156.10(a)(3). The foreign text must be a true and accurate translation of the English text.

Important Note: Foreign text may be used on all or part of the labeling.

Recycling of Containers

The Agency allows certain types of statements regarding the recycling of containers to be added to the label without prior notification. Refer to 40 CFR Part 156, Subpart H Container Labeling 156.140, 156.144, 156.146, and 156.156 for appropriate statements.

Minor Formulation Amendments

Although a formulation change may only be accomplished through submission of an application for amended registration, the Agency has developed an accelerated review process for certain minor formulation amendments.

The criteria for accelerated review are listed below, followed by a description of the review process.

> - Note that confirmatory efficacy data are not required for minor formulation amendments, **except for aerosols**.

Criteria for Accelerated Review

Amendments involving the following types of formulation changes will be considered eligible for accelerated review subject to the following limitations:

Addition, deletion, or substitution of one or more colorants in a formulation:

- the total percentage of changed colorant does not exceed 1 percent by weight of the formulation;
- the component(s) of the colorant are listed on EPA's Pesticide Inert Ingredient List <https://epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance>;
- the colorant has the appropriate exemption from the requirement of a tolerance under 40 CFR 180.910 – 180.960 if the product is registered for food use; and
- the product is not intended for use as a seed treatment or rodenticide.

Addition, deletion, or substitution of one or more fragrances in a formulation:

- the total percentage of changed, added or deleted fragrance does not exceed 1 percent by weight of the formulation;
- information on the composition of the fragrance has been provided to the Agency by the fragrance manufacturer or registrant;
- the fragrance has been determined to be acceptable for such use by the Agency at the proposed concentration or the component(s) of the fragrance are listed on EPA's Pesticide Inert Ingredient List <https://epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance>;
- the fragrance components are exempt from the requirement of a tolerance under 40 CFR 180.910 – 180.960 if the product is registered for food use; and
- the product is not intended for use in baits or repellents.

Addition, deletion, or substitution of one or more inert ingredients (other than fragrances or dyes) in a formulation:

- the nominal concentration of active ingredient does not change;
- the change does not invalidate any product-specific data submitted in support of the initial registration that causes additional data to be required;
- the identity of any proposed substitute inert ingredient is known by the registrant and is listed on EPA's Pesticide Inert Ingredient List <https://epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance>;
- the inert ingredient is exempt from the requirement of a tolerance under 40 CFR 180.910 – 180.960 if the product is registered for food use;
- any change involves inert ingredients used for the same purpose in the formulation (e.g., carrier, emulsifier, surfactant); and
- the product is not a bait or repellent and is not intended to be used to control pests of significance to public health.

Grounds for Denying Accelerated Review

Applications for the above kinds of amendments will not be considered for accelerated review if:

- a change would alter the product's acute toxicity category or physical/chemical characteristics such that label modifications become necessary; or
- a change would affect the product's efficacy such that supporting data become necessary (such as for vertebrate control products, tin-based antifoulant paints, food-contact surface sanitizers and liquid or aerosol insecticides intended for household use).

Submitting Minor Formulation Amendments

If a registrant believes that an amendment meets the criteria above, he/she should highlight this on the application for amended registration with a statement such as "**Minor Formulation Amendment per PR Notice 98-10**." The submission should be addressed to the appropriate regulatory division's Product Manager/Team Leader and to the address listed in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> and include:

AR0000492

- EPA Form 8570-1, Application For Pesticide Registration/Amendment <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>;
- one copy of the existing formulation, EPA Form 8570-4, Confidential Statement of Formula (CSF) <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>;
- two copies of the CSF of the proposed formulation;
- any supporting information such as the Material Safety Data Sheet (MSDS) on the added inert ingredient(s); and
- confirmatory efficacy data only if the product is an aerosol or bears a public health claim.

EPA will make every effort to prepare an appropriate response to the registrant either accepting or rejecting the amendment within 45 days of receipt of the application except when confirmatory data are submitted. Additional time is required for review of such data.

Final Printed Labeling

After acceptance of a new product registration, labeling amendment or labeling notification, final printed labeling must be submitted before the product is sold or distributed. Two copies of the final printed labeling that incorporate any labeling changes required by the acceptance letter and/or notification must be submitted.

Contacts for Additional Information

Any questions or need for additional information regarding notifications should be directed to the appropriate Product Manager assigned the product in question. Refer to Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> for a listing of Product Branches.

References Cited in Chapter 7

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>for information on the source of these documents.

Code of Federal Regulation, Title 40

AR0000493

- Part 152 - Pesticide Registration and Classification Procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 157 - Packaging Requirements for Pesticide and Devices
- Part 158 - Data Requirements for Registration
- Part 161 - Data Requirements for Registration of Antimicrobial Pesticides
- Part 180 - Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Foods

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 2 - Definitions
- Section 3 - Registration of pesticides
- Section 6 - Administrative review; suspensions
- Section 12 - Unlawful Acts

Pesticide Registration Notices <https://epa.gov/pesticide-registration/pesticide-registration-notices-year>

AR0000494

- PR Notice 83-3 <https://epa.gov/pesticide-registration/prn-83-3-label-improvement-program-storage-and-disposal-label-statements> Label Improvement Program – Storage and Disposal Statements
- PR Notice 84-1 <https://epa.gov/pesticide-registration/prn-84-1-clarification-label-improvement-program-farmworker-safety-and> Clarification of Label Improvement Program
- PR Notice 91-1 <https://epa.gov/pesticide-registration/prn-91-1-procedures-voluntarily-requesting-deletion-approved-uses-registered> Procedures for Voluntarily Requesting Deletion of Approved Uses from Registered Labels
- PR Notice 94-2 <https://epa.gov/pesticide-registration/prn-94-2-recycling-empty-aerosol-pesticide-containers> Recycling Empty Aerosol Pesticide Container
- PR Notice 97-4 <https://epa.gov/pesticide-registration/prn-97-4-consumer-access-numbers-pesticide-labels> Consumer Access Numbers on Pesticide Labels
- PR Notice 97-6 <https://epa.gov/pesticide-registration/prn-97-6-use-term-inert-label-ingredients-statement> Use of Term "Inert" in the Label Ingredients Statement
- PR Notice 98-10 <https://epa.gov/pesticide-registration/prn-98-10-notifications-non-notifications-and-minor-formulation-amendments> Notifications, Non-Notifications and Minor Formulation Amendments
- PR Notice 2007-1 <https://epa.gov/pesticide-registration/prn-2007-1-disposal-instructions-non-antimicrobial-residential-or-household> Disposal Instructions on Non-Antimicrobial Residential/Household Use Pesticide Product Labels
- PR Notice 2007-4 <https://epa.gov/pesticide-registration/prn-2007-4-labeling-revisions-required-final-rule-pesticide-management-and> Labeling Revisions Required by the Final Rule "Pesticide Management and Disposal Standards for Pesticide Containers and Containment

Label Review Manual <https://epa.gov/pesticide-registration/label-review-manual>

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 8 – Inert Ingredients

In this chapter:

- Inert Ingredients
- Regulation of Inert Ingredients
- New Inert Ingredients under PRIA 3
- Inert Ingredient Review Process
- Inert Mixture Products
- Pesticide Product Registration and Inert Ingredients
- Contacting the Chemistry, Inerts, and Toxicology Branch
- References Cited in Chapter 8

Inert Ingredients

Many pesticide products contain substances in addition to the active ingredient(s) that are referred to as inert ingredients or sometimes as "**other ingredients**." This chapter describes how EPA reviews inert ingredients as part of the pesticide product review process. For the most recent information and updates on this process, see the Inert Ingredients <https://epa.gov/pesticide-registration/inert-ingredients-regulation> Web page.

This Web page provides information on and links to:

- Inert Ingredient Frequently Asked Questions <https://epa.gov/pesticide-registration/guidance-documents-inert-ingredients>, which provides answers to commonly asked questions including guidance on finding approved food and nonfood inert ingredients and instructions for obtaining a trade name or mixture in the Agency database.

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

- Guidance documents for submitting a request for approval of a new or amended food use, nonfood use and Low Risk Polymer inert ingredient.

    - Food - "General Guidance for Petitioning the Agency for the Establishment of a New/Amended Food Use Inert Ingredient Tolerance or Tolerance Exemption <https://epa.gov/pesticide-registration/guidance-documents-inert-ingredients>"
    - Nonfood - "General Guidance for Requesting a New Nonfood Use Inert Ingredient <https://epa.gov/pesticide-registration/guidance-documents-inert-ingredients>"
    - Low Risk Polymer - "Guidance to Petitioners for Low Risk Polymer Submissions <https://epa.gov/pesticide-registration/guidance-documents-inert-ingredients>"

- A page listing inert ingredients permitted for use in pesticide products including a list of food-use, nonfood-use, 25(b) and organic inert ingredients <https://epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance>.
- Completed inert ingredient tolerance reassessment decision documents <https://epa.gov/ingredients-used-pesticide-products/inert-ingredients-reassessment-decision-documents>.
- The Fragrance Ingredient List <https://epa.gov/pesticide-registration/guidance-documents-inert-ingredients>.

EPA plans to continue to post additional guidance and documents for inert ingredients on the Web page. Therefore, regular visits to the Web page are recommended.

Section 2(m) of FIFRA defines an inert ingredient as "an ingredient which is not active." EPA further describes an inert ingredient in 40 CFR 152.3 as "any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product, except as provided by 40 CFR 174.3." Inert ingredients may be, for example, solvents, carriers, aerosol propellants, fragrances, and dyes.

Regulation of Inert Ingredients

The registration and reregistration of pesticide products under FIFRA include a determination that the pesticide product formulation meets the registration standard under FIFRA section 3 (including the lack of unreasonable adverse effects on the environment). The entire formulation, including the inert ingredients, must meet this standard. In addition, the Federal Food, Drug, and Cosmetic Act (FFDCA)

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. **Inert Ingredients**
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>

<https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> requires that inert ingredients in pesticide products used on food and feed crops, agricultural commodities, or livestock must have a tolerance or tolerance exemption under 40 CFR Part 180. Inert ingredient approval submissions are now covered categories under PRIA 3. See the PRIA 3 Fee Schedule Tables <https://epa.gov/node/53395/> or the Fee Determination Decision Tree <https://epa.gov/pria-fees/pria-4-fee-determination-decision-tree> for descriptions of these inert categories, their PRIA 3 fees and corresponding decision review timeframes.

New Inert Ingredients under PRIA 3

Under PRIA 3 there are ten inert ingredient categories that cover new food, nonfood, low risk polymer inert ingredients as well as amendments to previously approved inert ingredients and nonfood inert ingredients that are substantially similar to approved inert ingredients. See the PRIA 3 Fee Schedule Tables <https://epa.gov/pria-fees/fy-2023-2024-fee-schedule-registration-applications> or the Fee Determination Decision Tree <https://epa.gov/pria-fees/pria-4-fee-determination-decision-tree> for descriptions of these ten covered inert categories, their PRIA 3 fees and corresponding decision review timeframes.

PRIA 3 allows new inert ingredients to be submitted in conjunction with a new active ingredient or first food use application. Each component of such a joint application would be charged its appropriate PRIA fee, but the decision review timeframe for the joint application would be that of the PRIA category with the longer timeframe, which in most cases would be the new active ingredient or first food use.

PRIA 3 also allows for the submission of covered applications that are associated with and dependent upon a currently pending inert ingredient action. The decision review timeframe for the associated covered application will be extended to match the timeframe for the pending inert action unless the PRIA due date for the associated application is further out, in which case it will be subject to its own decision review timeframe.

For approval of a new inert ingredient intended for use in a food-use pesticide product, see “General Guidance for Petitioning the Agency for the Establishment of a Tolerance or Tolerance Exemption under PRIA 3 <https://epa.gov/pesticide-registration/guidance-documents-inert-ingredients>”. EPA recommends that parties interested in establishing a tolerance or tolerance exemption for a new inert ingredient first consult with the Agency to determine the adequacy of available data and/or the need for additional data.

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

For approval of a new inert ingredient intended for use in a nonfood-use pesticide product, see "General Guidance for requesting the Approval of a New Nonfood Use Inert Ingredient or Amending a Currently Approved Nonfood Use Inert Ingredient under PRIA 3 <https://epa.gov/pesticide-registration/guidance-documents-inert-ingredients>".

For approval of a new low risk polymer see "General Guidance for Requesting the Establishment of a Tolerance Exemption for a Low Risk Polymer or Nonfood Use Approval of a Low Risk Polymer under PRIA 3 <https://epa.gov/pesticide-registration/guidance-documents-inert-ingredients>".

Inert Ingredient Review Process

The Agency screens all PRIA submissions during a 21-day Content Screen for adequacy/completeness upon receipt. Submission packages not deemed acceptable are returned to the applicant to correct the deficiency. The PRIA decision review time period begins 21 days after receipt of the application (i.e. after the 21-day Completeness Screen).

In addition to the 21-day Content Screen, under PRIA 3 the Agency also conducts a Preliminary Technical Screen of the application to determine if the data and information submitted in the application are accurate, complete and appear to be consistent with the request such that a full and complete assessment can be conducted. This screen is concluded no later than 45 days after the start of the decision review period for actions with decision review time periods less than or equal to six months and no later than 90 days after the start of the decision review period for actions with decision review periods greater than six months.

After the review and risk assessment are completed, a decision will be made regarding the safety of the inert ingredient in question. For food use inerts for which a tolerance or tolerance exemption will be granted, a final rule outlining IIAB's decision will be published in the Federal Register. After the rule is published granting the use of the inert, the inert ingredient will be permitted for use under the appropriate use pattern. For nonfood use inerts a letter outlining IIAB's decision will be emailed to the submitter. After issuance of this letter granting the use of the nonfood use inert, the inert will be permitted for use under the appropriate use pattern.

Inert Mixture Products

Pesticide applicants typically include individual inert ingredients in their pesticide products. In addition, applicants often purchase products containing a mixture of inert ingredients and add them to their pesticide products. For example, applicants may buy surfactants and anti-foaming agents made by other companies. These products may be mixtures containing multiple

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

inert ingredients. Just as with individual inert ingredients, each component in a mixture must be approved for use by the Agency. It is the applicant's responsibility to ensure that EPA has sufficient information about the inert mixture the applicant wishes to use.

When the composition of a mixture product is held as proprietary by the company that sells the mixture to the applicant, the Agency establishes a Master File for the mixture that contains the complete compositional information. If an applicant wishes to use a proprietary inert mixture as part of its product formulation, the following information should be submitted on the letterhead of the manufacturing company:

- The full product name and, for each component* in the mixture, its chemical name, CAS Registry Number, and percentage by weight.
- The total percentage by weight for all components must total 100%.

Items submitted for inclusion in the Master File may be claimed as confidential business information (CBI). Information claimed as confidential will be treated in accordance with established procedures for handling FIFRA CBI. To assure proper routing and processing, the cover letter should identify the submission as inert ingredient mixture information.

*Please note - If the product contains a component that is itself a mixture or trade name product, EPA needs to receive the above information for all of the proprietary products. If there are impurities remaining in the final product, those components should be listed as such along with their percentage in the final formulation.

Formulators sometimes have difficulty determining whether a trade name product is permitted for use as an inert ingredient. EPA is offering companies an opportunity to add their trade name product to a list for posting on EPA's web page, along with the uses for which it is approved, and possibly the manufacturer's name. The public listing will **not** include any information related to the composition of trade name inert ingredients, **nor** products they are used in.

Pesticide Product Registration and Inert Ingredients

Pesticide applicants who would like to use a chemical or substance as an inert ingredient in their pesticide product should first ensure that it has been approved by EPA or is currently pending before the Agency for approval. As part of the Agency's review of an application for the registration of a pesticide product, the product's composition information will be examined to verify that all of the inert ingredients proposed for use in the pesticide formulation have been approved by the Agency or are currently pending before the Agency for approval.

All Confidential Statements of Formula (CSF) submitted with a new or amended pesticide registration application for conventional pesticides, antimicrobial pesticides, and biopesticides are screened to ensure that all inert ingredients are approved for the labeled use of the pesticide product or are currently pending before the Agency for approval. If an inert ingredient is not currently approved for the intended use of the pesticide formulation nor currently pending before the Agency for approval and the application is covered by PRIA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees> (FIFRA section 33) but does not contain the data necessary for the Agency to make a decision on the inert ingredient, then the submission will be rejected and a portion of the PRIA fee will be retained.

AR0000504

If a new inert ingredient is part of an application for registration of a new conventional chemical product, the PRIA 3 fee category will be I001 or I008 for a food use <https://epa.gov/pria-fees/pria-fee-category-table-inert-ingredients> and I004 or I009 for a nonfood use <https://epa.gov/pria-fees/pria-fee-category-table-inert-ingredients> product. If a new conventional product is submitted and it requires an amendment to an existing inert tolerance exemption (e.g. adding post-harvest use) it will fall under the PRIA 3 fee category I002, I003 or I010. If a new product is submitted and it requires an amendment to an approved inert use pattern, it would fall under the PRIA 3 fee category of I005 or I006. Another category of pesticide application involving a request to approve an inert ingredient that is covered by PRIA 3 is a request to approve a Plant Incorporated Protectant inert ingredient such as a marker protein with a fee category of B903 <https://epa.gov/pria-fees/b903-pria-fee-category>.

The Agency's current process for confirming the approval status of an inert ingredient included within other types of applications covered by PRIA are described in Footnote A of the 21 Day Content Screen Review Worksheet <https://epa.gov/pria-fees/pria-21-day-content-screen-worksheet>. To avoid unnecessary delays and possible loss of fees, it is strongly recommended that applicants confirm the approval status of all components in their new product before submitting a registration application. Approved inert ingredient tolerances and tolerance exemptions are found in the Code of Federal Regulations (CFR) under 40 CFR Part 180. Links to inert ingredients approved for nonfood uses are listed on the Inert Ingredients Web page <https://epa.gov/pesticide-registration/inert-ingredients-regulation>.

Contacting the Chemistry, Inerts, and Toxicology Branch

The staff of the Chemistry, Inerts, and Toxicology Assessment Branch (CITAB) (formerly the Inert Ingredient Assessment Branch) is available to assist you with your questions. The Branch's e-mail address is: Inert Ingredient Assessment Branch (inertsbranch@epa.gov).

Information is also available on the Inert Ingredients Web page <https://epa.gov/pesticide-registration/inert-ingredients-regulation>. If you need further assistance contact CITAB Chief, PV Shah at shah.pv@epa.gov or (703) 308-1846.

References Cited in Chapter 8

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on how to obtain these documents.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide Registration and Classification Procedures
- Part 174 - Procedures and Requirements for Plant-Incorporated Protectants
- Part 180 - Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 2 Definition

Federal Food, Drug and Cosmetic Act <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>

- Section 408 - Tolerances and Exemptions for Pesticide Chemical Residues

Inert Ingredients Web page <https://epa.gov/pesticide-registration/inert-ingredients-regulation>.

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 28, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 9 – Supplemental Distribution of a Registered Pesticide

In this chapter:

- Supplemental distribution of a registered pesticide
- Requirements for approval of supplemental distribution
- Cancellation of a distributor product
- Concerning a supplemental registration of a distributor product
- Where to request a company number
- Where to request an establishment registration
- Contacts for more information
- References cited in chapter 9

Supplemental Distribution of a Registered Pesticide

According to 40 CFR 152.132, registrants may distribute or sell their registered product under another company's name and address instead of (or in addition to) their own. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "supplemental registration" or "distributor product." The distributor, also known as a "subregistrant," is considered an agent of the registrant, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product.

Detailed information on the supplemental distribution or supplemental registration of another federally registered product can be found in 40 CFR 152.132.

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Important Note: Supplemental registrations are only an extension of a currently federally registered pesticide product. They are a duplication of the basic registered product and must reflect any changes in formulation or labeling made to the basic registered product within the same timeframe imposed on that product.

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. **Supplemental Distribution of a Registered Pesticide**
10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

AR0000513

- If the basic registered product is canceled, the supplemental registration is automatically canceled effective on the same date as the basic registered product, and existing stocks must be sold in the same time period (40 CFR 152.132(e)).
- If the basic registered product is transferred to another company, supplemental distributorships do not transfer with the section 3 registration. Registrants must notify all supplemental distributors of the transferred product of the transfer agreement.
- If the new basic registrant wishes to continue any supplemental distributorship or add new ones, the basic registrant must fill out a new "Notice of Supplemental Distribution of a Registered Product" Form 8570-5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>.

Requirements for Approval of Supplemental Distribution

The following conditions must be met before EPA will permit supplemental distribution of a federally registered pesticide product:

- The registrant of the federally registered product for which a second party wishes to obtain supplemental registration must have submitted to the Agency a statement (EPA Form 8570-5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, Notice of Supplemental Registration of Distributor) in triplicate signed by both the registrant of the basic registered product and the second party ("the distributor"). Refer to 40 CFR 152.132(a) The basic registrant is the **only one** who can submit EPA Form 8570-5 as explained in 40 CFR 152.132(a) and in the EPA Form 8570-5 instructions. The application, which includes the 8570-5 form and a cover letter must include the following information:

  - the cover letter must have the name and address of the registrant of the basic registered product;
  - the 8570-5 form must have the basic registered product and the registration number of the federally registered product; and
  - the name and address of the distributor, the distributor's company number, and the name of the distributor product. If EPA has not already assigned the distributor a company number, one will be assigned upon written request, and must be assigned before 8570-5 is completed and submitted. Refer to Chapter 14 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>, or below, for obtaining a company number; and to Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> for the address and distribution code when submitting.

  Applications that are incomplete or that contain errors will be returned with a checklist explaining the reason for rejection or disapproval.
- The distributor product is produced, packaged, and labeled in a registered establishment operated by the same producer (or under contract with basic producer according to 40 CFR 152.30) who produces, packages, and labels the basic registered product (40 CFR 152.132(b)).

AR00005514

- The distributor product may not be repackaged. It must remain in the basic registrant's or producer's original, unopened container. Refer to Chapter 14 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>, which explains how to obtain an establishment registration.
- The labeling associated with the distributor product must be the same as that of the basic registered product, with the following exceptions:

    - the product name of the distributor's product may be different from that of the registrant's, but it may not be misleading (40 CFR 152.132(d)(1);
    - the name and address of the distributor's company may appear instead of the registrant's name and address (a phrase such as “Distributed by...” must be used) (40 CFR 152.132(d)(2)), and 40 CFR 156.10(c));
    - the EPA registration number of the basic registered product must be followed by a hyphen, followed by the distributor's company number (e.g., if the registration number of the registrant's product is EPA Reg. No. 999999-88888, and the distributor's company number is 777777, then the distributor's number appearing on the label should be EPA Reg. No. 999999-88888-777777) (40 CFR 152.132(d)(3));
    - the establishment number on the label must be that of the final establishment at which the basic registered product was produced, which includes packaging and/or repackaging for sale (40 CFR 152.132(d)(4)); and
    - any specific claims on the registrant's label, such as the sites of application or pests to be controlled, may be omitted from the distributor's product label provided that no changes are necessary in any of the precautionary or other labeling of the basic registered product (40 CFR 152.132(d)(5)).

Important Note: The distributor, also known as a “subregistrant,” may not make additions to the registrant’s basic product label (i.e., add claims, additional sites, or pests).

Cancellation of a Distributor Product

When a registrant enters into a relationship with a supplement distributor, for each product involved, the registrant must submit to the Agency a statement (8570-5 form) signed by both registrant and supplemental distributor that lists the names and addresses of the distributor, the distributor’s company number, any additional brand names to be used, and the registration number of the basic product (40 CFR 152.132(a)). Providing a complete Form 8570-5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms> fulfills this requirement. Since the basic registrant is the **only one** who can submit EPA Form 8570-5 as explained in 40 CFR 152.132(a) and in the EPA Form 8570-5 instructions. A cover letter from the basic registrant including their address and reason for the application will aid in the Agency’s approval process. Just as the registrant’s product (“the basic registration”) may have alternate brand names, a Supplemental (Distributor) Product can have multiple names associated with a product.

If a basic registrant voluntarily cancels its basic product registration, 40 CFR 152.132(e) states all distributor products distributed or sold under that registration number are also canceled and that the registrant is responsible for notifying all distributors of the terms and conditions of cancellation.

In addition to instances when a basic registration is voluntarily canceled, and therefore all distributor products are canceled, the registrant may wish to notify the Agency that a supplemental distributor relationship has ended. In this situation the basic registration remains but the distributor product(s) is/are canceled. There are also times when the basic registrant and/or distributor wants to remove a brand name from a distributor product while keeping both the basic and distributor registrations active. The Agency requests that these types of notifications be provided by letter. To assure efficient processing, when notifying the Agency of the end of a supplemental distributor relationship, the following should be included in the subject line and body of the request letter:

"Notification of Termination of Supplemental Distributor Agreement," then add the PRODUCT NUMBER including the distributor company number for which the relationship has ended. This will terminate all distributor products associated with the cited registrant's product and distributor company number.

When notifying the Agency of changes to the brand name of a supplemental distributor product, the following should be included in the subject line and body of the request letter:

"Notification of [Removal and/or Change] of Distributor Product Name," then add the PRODUCT NAME you would like removed or changed.

Please note, when a basic registrant terminates a supplemental registration, EPA interprets 40 CFR 152.130(c) to generally permit a supplemental distributor 18 months to sell and distribute existing stocks after the basic registrant terminates the supplemental registration. In this context, the supplemental registrant's existing stocks are only those affected pesticide products that have been released for shipment as of the effective date of termination of the subject supplemental registration. Sale or distribution of any quantities of the affected distributor product produced after the effective date of termination would be considered illegal under FIFRA.

It is important to note that while EPA regulations and policy may permit such distribution or sale of existing stocks for 18 months following termination of the supplemental distribution, the contractual arrangement between the basic registrant and the supplemental distributor may contain terms that further limit or preclude sale and distribution by the supplemental distributor (although such contractual arrangements would be enforceable through the courts, and not by EPA). The registrant and supplemental distributor are equally liable for any violations that occur during the 18 months during which the existing supplemental product can be sold, unless a contractual arrangement between the two limits the existing stocks period. The ability for the supplemental distributor to sell and distribute is linked to the liability of the basic registrant.

If the supplemental distributor is legally selling and distributing, the basic registrant is still liable for any violations. The basic registrant would not, however, be liable for any violations stemming from distributor product that is produced after the termination of the relationship.

After the relationship between basic registrant and supplemental distributor is officially and totally terminated (either by the passing of 18 months after the basic registrant notified the Agency of the end of the relationship or by a contract that finally ends the relationship earlier by disallowing existing stocks), the basic registrant is no longer liable for any violations that occur based on the distributor's product.

Concerning a Supplemental Registration of a Distributor Product

The registrant of the basic registered product should submit the completed application (cover letter and 8570-5 form) and any subsequent requests or notifications via the Pesticide Submission Portal (PSP): https://cdx.epa.gov/epa_home.asp <https://cdx.epa.gov/epa_home.asp> or to Shirley Burgess (burgess.shirley@epa.gov).

For more information on electronic submissions of pesticide applications go here <https://epa.gov/node/29751>.

Please note, these items should **not** be directed/sent to the registering division or product manager.

Where to Request a Company Number

To obtain an EPA assigned company number go here <https://epa.gov/node/37715>.

Where to Request an Establishment Registration

Information on how and where to register an establishment (pesticide product producing facility) may be found on the Pesticide Establishment Registration and Reporting <https://epa.gov/compliance/pesticide-establishment-registration-and-reporting> Web page and Chapter 14 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>.

Contacts for More Information

For further information, please contact Shirley Burgess (burgess.shirley@epa.gov) or by calling 703-308-8628.

References Cited in Chapter 9

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the sources of these documents.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide registration and classification procedures
- Part 156 - Labeling requirements for pesticides and devices

EPA Form 8570-5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms> - Notice of Supplemental Registration of Distributors

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 28, 2023



AR00005 19

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 10 – Data Compensation Requirements

In this chapter:

- Introduction
- FIFRA Provisions Relating to Data Compensation Obligations
- Expansion of Exclusive-Use Rights by FQPA
- Complying with Data Compensation Procedures
  - Methods for Complying with the Data Compensation Requirements of FIFRA Section 3(c)(1)(F)
  - Categories of Data
  - When Materials Must Be Submitted to the Agency
  - The Cite-All Method of Support
  - The Selective Method of Support
- Data Compensation Charges/Payment Disputes
  - Petitions to Cancel Registration
- Questions and Answers
- Contacts for Additional Information
- References Cited in Chapter 10

Introduction

This chapter describes the information that an applicant must submit with the application for registration, amended registration, reregistration or registration review to comply with the provisions of FIFRA section 3(c)(1)(F) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>. This chapter also describes the procedures by which data submitters may challenge registration actions that allegedly failed to comply with these procedures. Addressing data compensation obligations is a critical part of the registration and reregistration processes. If the

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Agency determines that an applicant has failed to comply with the requirements in FIFRA and its implementing regulations, the application may be denied or a registration previously issued may be canceled.

FIFRA Provisions Relating to Data Compensation Obligations

A substantial amount of scientific data and information are required to support the registration of a pesticide. These data and information can be very costly to the data submitter. To protect the interests of data submitters, Congress included provisions in FIFRA that provide data submitters certain rights to the data they submit to EPA. In particular, FIFRA section 3(c)(1)(F) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> provides for both "exclusive-use" and compensation rights in data submitted to EPA to support registration actions.

"Exclusive-use" treatment for data means that the data may not be relied upon by other applicants or registrants to support FIFRA registration and reregistration actions without the permission of the data submitter. As a general matter, exclusive-use protections apply to those data that are submitted to support the initial registration of a product containing a new active ingredient. A 10-year period of protection for such data begins from the date of the original registration of the pesticide. This 10-year period of protection also extends to data submitted solely to support the addition of any new use to that registration during the 10-year period (note that such new use data are entitled to exclusive-use treatment only for the balance of the 10-year period remaining following addition of the new use to the registration).

While exclusive-use rights apply to data submitted to EPA in support of the first registration of a pesticide, "compensation" rights extend to all data necessary to support or maintain a registration or that are necessary to support of an experimental use permit. Applicants and registrants may not rely on data that retain compensation rights to support registration or reregistration unless they have first offered the data submitter compensation for the use of such data. Section 3(c)(1)(F) provides for a 15-year period of protection for such data following the date of submission of that data to the Agency. There is a more detailed discussion below describing how the Agency protects data rights.

---

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>
10. **Data Compensation Requirements**

Expansion of Exclusive-Use Rights by FQPA

The Food Quality Protection Act (FQPA) of 1996 <https://epa.gov/node/111505> amended the data protection rights section of FIFRA by expanding exclusive-use rights. Under FIFRA section 3(c)(1)(F)(ii) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, the Agency may extend the 10-year period of exclusivity for a period of up to three years by the addition of new minor uses to the original registration (three minor uses required for each additional year of exclusive-use protection). The new minor uses must have been **registered** within seven years of the date the original registration was granted to qualify and they must also meet at least one of the statutory criteria (e.g., there are insufficient efficacious alternatives registered).

It is the registrants' responsibility to request the extension. Registrants must also provide information to the Agency explaining how they meet the applicable statutory criteria in order for EPA to determine whether the registration is entitled to the extension of exclusive-use protection rights. Read more about expanding exclusive-use rights <https://epa.gov/pesticide-registration/details-exclusive-use-data-protection-minor-use-registrations>.

FQPA also amended the FIFRA data protection provisions by adding section 3(c)(1)(F)(vi) that provides the Agency with the authority to afford exclusive-use protection to data submitted by an applicant, or by a registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use. The data associated with the new minor use are entitled to 10 years of exclusive-use protection from the date the data are submitted if the data relate solely to a new minor use. In order to obtain the exclusive-use protection, the applicant or registrant **must at the time the new use is requested** notify the Agency that to the best of its knowledge the exclusive-use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide are eligible for the protection under this section of FIFRA.

Important Notes: The registrant or applicant must request the exclusive-use protection of section 3(c)(1)(F)(vi) at the time they request the amendment for the new minor use.

Under 3(c)(1)(F)(ii), as appropriate, EPA shall modify or terminate the exclusive-use period if the registrant voluntarily cancels the product or deletes from the registration the minor uses that formed the basis for the extension of exclusive use, or if EPA determines that the registrant is not actually marketing the product for such minor uses.

---

11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

Complying with Data Compensation Procedures

As stated in 40 CFR 152.81(a), data compensation procedures apply to each application for:

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- registration of a new product;
- amendment to add a new use to an existing product registration; and
- reregistration and registration review of an existing product.

However, (a) is limited by 40 CFR 152.81(b) in that data compensation procedures ***do not*** apply to the following types of applications:

- applications for registration submitted by states under FIFRA section 24(c);
- applications for experimental use permits under FIFRA section 5;
- applications for emergency exemptions under FIFRA section 18; and
- applications to make only one or more of the following types of amendments to existing registrations, unless the consideration of scientific data would be necessary in order to approve the amendment under FIFRA section 3(c)(5) per 40 CFR 152.81(b)(4)
  - an increase or decrease in the percentage in the product of one or more of its active ingredients or deliberately added inert ingredients;
  - a revision of the identity or amount of impurities present in the product;
  - the addition or deletion of one or more deliberately added inert ingredients;
  - the deletion of one or more active ingredients;
  - a change in the source of supply of one or more of the active ingredients used in the product, if the new source of the active ingredient is a product which is registered under FIFRA section 3;
  - deletion of approved uses of claims;
  - redesign of the label format involving no substantive changes, express or implied, in the directions for use, claims, representations, or precautionary statements;
  - change in the product name or addition of an additional brand name, if no additional claims, representations, or uses are expressed or implied by the changes;
  - clarification of directions for use;
  - correction of typographical errors;
  - changes in the registrant's name or address;
  - adding or deleting supplemental registrants;
  - changes in the package or container size;
  - changes in warranty, warranty disclaimer, or liability limitation statements, or addition to or deletion of such statements;
  - “splitting” a label for the sole purpose of facilitating the marketing of a product in different geographic regions with appropriate labels, where each amended label will contain previously approved use instructions (and related label statements) appropriate to a particular geographic region;
  - any other type of amendment, if the Administrator or his designee determines, by written finding, that the Agency consideration of scientific data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5); and
  - compliance with Agency Regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be suspended or cancelled, or that a hearing will be held under FIFRA section 6. (However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA section 3(c)(2)(B) or because of failure to submit data.)

Methods for Complying with the Data Compensation Requirements of FIFRA Section 3(c)(1)(F)

In order for the Agency to evaluate an application for registration or to amend a registered product, the applicant generally must either submit its own data or cite to data previously submitted by it or others that cover the required data to support the application or amendment. 40 CFR 152.80-99 and 152.116-119 provide detailed information on how to comply with the data compensation provisions of FIFRA section 3(c)(1)(F).

The methods for complying with data requirements may be addressed in one of two ways and are discussed in detail in this chapter:

- **Cite-All:** The applicant cites to all the data in the Agency files that are pertinent to EPA's consideration of the requested registration action. See 40 CFR 152.86.
- **Selective Method**: The applicant lists the specific data requirements that apply to its product, its active ingredients, and use patterns and then selectively cites to individual studies, including the applicant's own data. The selective method also allows an applicant to "cite all" data in the Agency's files to satisfy specific data requirements (commonly referred to as "selective cite-all"). See 40 CFR 152.90(b)(5).

Categories of Data

FIFRA section 3(c)(1)(F) establishes three categories of data and the regulations and legislative history provide further information on each:

- **Exclusive-Use Data**. Under FIFRA section 3(c)(1)(F)(i), data submitted to the Agency in support of the initial registration of a new active ingredient, a new combination of active ingredients, or in support of an application to amend the original registration to add a new use have "exclusive-use" protection for a period of 10 years after the date of the initial registration. The Agency cannot consider these data in support of an application for registration or amendment to a registration unless written authorization from the original data submitter is obtained authorizing the Agency to use these data to support the application. After the "exclusive" use period has expired, the owner of the data may still be entitled to compensation as described below. See 40 CFR 152.83(c) and 40 CFR 152.116.

As described above, FIFRA sections 3(c)(1)(F)(ii) and (vi) provide for extensions of the 10-year period and establish exclusive-use protection for certain minor use data where the data no longer retain exclusive-use protection, respectively.

AR0000528

- **Compensable Data**. The Agency may, without the permission of the original data submitter, consider data that: (1) no longer retains exclusive-use protection, (2) were submitted to support an application, and (3) are within the 15-year compensatory period (period begins on the date the data were originally submitted to EPA), as long as the applicant/registrant relying on these data has certified to the Agency that it has offered to pay compensation to the original data submitter(s). In addition, the applicant must provide a notification to the registrants who own the data being relied upon of its intent to apply for registration, including the name of the proposed product, and a list of the product's active ingredients.
- **All Other Data**. Data not falling into the first two categories (e.g., public literature articles, government-generated studies, and data for which all periods of exclusive use and compensation have expired) may be cited by an applicant without permission or an offer of compensation. However, the applicant or registrant is still required to submit a data compensation certification form. See 40 CFR 152.94.

* Note that when a study is developed jointly with government and private resources, the private component may be compensable under certain circumstances. For further information, see Question and Answer 13 below.

When Materials Must Be Submitted to the Agency

Information and materials required to demonstrate compliance with data compensation procedures must be submitted at the time of application (40 CFR 152.84), unless it is determined that data compensation procedures do not apply to the application 40 CFR 152.81(b).

The Cite-All Method of Support

Applicants may comply with the data compensation requirements under the cite-all method (40 CFR 152.86 and 40 CFR 152.95) for an application to register a new product or to amend or reregister a product by:

- citing all pertinent data in the Agency's files and making appropriate offers to pay compensation. If exclusive-use data are being used, written permission from the original data submitter is required.

Information to be submitted if an applicant chooses the cite-all method of support:

- Certification with Respect to Citation of Data (EPA Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>)

  Except for applications for amendments that require no supporting data, applicants must complete this form to indicate how they will meet their data submission/data citation obligations under FIFRA. When a registrant relies on another company's data, it generally must certify that an offer of compensation has been made to the original data submitter or that it has the original data submitter's permission to cite the data. For further information on how to comply with data compensation requirements see FIFRA section 3(c)(1)(F), 40 CFR 152, Subpart E and the PRIA Web page.

  - Check the first box in section I, indicating the cite-all method of support; and
  - Check the box in section II indicating a general offer to pay compensation to other data submitters to the extent required by FIFRA section 3(c)(1)(F).

- Data Matrix (EPA Form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>)

  Applicants/registrants must include with the data certification form a completed list of companies sent offers of compensation. Data Matrix (EPA Form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) should be used for this purpose.

  When submitting a Certification with Respect to Citation of Data (EPA Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) under the cite-all method, the data matrix should indicate the companies to whom offers of compensation were made.

  There are two different copies of Form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>: the "Public File Copy" and the "Agency Internal Use Copy." The Agency Internal Use Copy is normally retained for Agency use but is available by request under the Freedom of Information Act (FOIA) <https://epa.gov/foia>. The Public File Copy will not contain the guideline reference number, the guideline study name, and the MRID number but will indicate the submitter and status of the data. (MRID numbers are not confidential.) This version of the data matrix will be available for public inspection along with Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms> once a product is registered.

  Important Note: The data tables and bibliography in an applicable Registration Standard and/or Reregistration Eligibility Document can be very helpful in developing a data matrix.

The Selective Method of Support

Applicants may comply with the data compensation requirements under the selective method by listing the specific data requirements that apply to their product (its active ingredients and/or use patterns) and by demonstrating compliance with the data requirements by either submitting the actual studies, citing individual studies, or by demonstrating that no study has been previously submitted to the Agency (a data gap). The selective method also allows an applicant to "cite all" data in the Agency's files to satisfy specific data requirements. This is known as the "cite-all" option under the selective method. Please refer to 40 CFR 152.90 for a detailed discussion of the selective method.

Important Note:The Data Gap option is not available to certain applicants, i.e., those seeking the registration of a product containing a new active ingredient or those seeking to add a new use pattern to a registered product. Please refer to 40 CFR 152.96 for additional information on documentation of a data gap.

- Certification with Respect to Citation of Data (EPA Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>)

  Except for applications for amendments that require no supporting data, applicants must complete this form to indicate how they will meet their data submission/data citation obligations under FIFRA. When a registrant relies on another company's data, it generally must certify that an offer of compensation has been made to the original data submitter or that it has the original data submitter's permission to cite the data. For further information on how to comply with data compensation requirements see FIFRA section 3(c)(1)(F) and 40 CFR 152, Subpart E and the PRIA Web page.

  - Check the second box in section I, indicating the selective method of support.
  - Check the box in section II indicating a general offer to pay compensation to other data submitters to the extent required by FIFRA section 3(c)(1)(F) if using the cite-all option under the selective method of support.

- Data Matrix (EPA Form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>)

  Include with this form a completed list of data requirements. Data Matrix (EPA Form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) must be used for this purpose. See PR Notice 98-5 <https://epa.gov/pesticide-registration/prn-98-5-new-forms-certification-respect-citation-data>.

Data Compensation Charges/Payment Disputes

FIFRA sections 3(c)(1)(F)(iii) and 3(c)(2)(B)(iii) state that the terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant or, failing such agreement, by binding arbitration under the procedure and rules of the Mediation and Conciliation Service. EPA is not involved with such disputes or the

AR0000531

procedures for arbitration. The arbitrator is to be appointed from the roster of arbitrators maintained by such Service.

The findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. Please refer to 29 CFR Part 1440 for details on the arbitration procedures.

Petitions to Cancel Registration

40 CFR 152.99 describes the procedures by which data submitters may challenge registration actions that allegedly failed to comply with FIFRA section 3(c)(1)(F).

Grounds for petition.

If an applicant has offered to pay compensation to an original data submitter of a study (either specifically or by filing a general offer to pay statement), the original data submitter may petition the Agency to deny or cancel the registration for any of the following reasons 40 CFR 152.99(a)(1):

1. the applicant failed to reach an agreement on the amount and terms of compensation;
2. the applicant failed to comply with the terms of an agreement on compensation;
3. the applicant failed to participate in an arbitration proceeding; or
4. the applicant failed to comply with the terms of an arbitration decision.

When no offer to pay has been made, grounds for challenge include but are not limited to the following 40 CFR 152.99(a)(2):

1. the applicant has failed to list a data requirement applicable to its product, or has failed to demonstrate compliance with all applicable data requirements;
2. the applicant has submitted or cited a study that is not valid;
3. the applicant has submitted or cited a study that does not satisfy the data requirement for which it was submitted or cited;
4. the applicant has failed to comply with the procedure for showing that a data gap exists;
5. the applicant has improperly certified that a data gap exists (An original data submitter who has failed without good cause to respond to an applicant's request for confirmation of a data gap may not petition the Agency for review on this basis.); or
6. the applicant has submitted or cited a study originally submitted by the petitioner, without the required authorization or offer to pay.

Timing of Petition 40 CFR 152.99(b)

A petition under paragraph (a)(1) above may be filed at any time that the circumstances warrant. A petition under paragraph (a)(2) above must be filed within one year after the Agency makes public the issuance of the registration.

AR0000533

Questions and Answers

The following questions reflect those most frequently asked inquiries regarding data compensation procedures:

1. **What data compensation information does the Agency require for a product or an amendment under the Cite-All Method of Support?**

   The Agency requires a completed and signed Certification With Respect to Citation of Data (EPA Form 8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) including a completed list of companies sent offers of compensation. Data Matrix (EPA Form 8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) should be used for this purpose. The PRIA Web page provides information on the contents of an application <https://epa.gov/pria-fees>. Information on exclusive use and data rights extensions can be found on the minor use Web page <https://epa.gov/pesticide-registration/minor-uses-and-grower-resources>.

2. **What are the data compensation requirements when submitting an application for an amendment to the registration of a product, when the Selective Method of Support is selected?**

   If an applicant wishes to use the Selective Method of Support, the Agency requires a completed and signed Certification With Respect to Citation of Data (EPA Form 8570-34 (PDF) <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) and a Data Matrix (EPA Form 8570-35 (PDF) <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>) with appropriate information showing how each data requirement is to be satisfied for the amendment, taking into consideration the most up-to-date information, i.e., the data tables and bibliography in the most recent Registration Standard or Reregistration Eligibility Document (if any) and the data requirements in 40 CFR Part 158 and for antimicrobials, 40 CFR 161. The PRIA Web page provides information on the contents of an application. <https://epa.gov/pria-fees>

   If a data matrix previously submitted in support of the product's initial registration or amendment is still valid, and no additional data are required, an applicant may reference that data matrix in support of its current applications for amended registration. If additional data are required to support their current amendment requests, then an updated data matrix must be submitted.

3. **Does an applicant requesting a registration for 100% repackaging of a registered technical grade, manufacturing-use or end-use product qualify for a formulators' exemption?**

   Yes, within the limits prescribed in 3(c)(2)(D) and 40 CFR 152.85. Other than the formulators' exemption form, no other data compensation form needs to be submitted to EPA. Under 40 CFR 152.116, if the registered product to be repackaged has exclusive-use data associated with it, OPP will send a Notice of Intent to register the product to the original data submitter(s).

4. **When submitting an application for an amendment to the registration of a product, and data are required to support the proposed amendment, does an applicant have to once again offer to pay compensation for all of the data necessary to support the amendment?**

   Yes. The entire product is subject to the data compensation provisions, including any amendment. There are several reasons for this requirement:

   - either generic data or product-specific data may have been submitted to the Agency to fill data gaps since the first offer to pay compensation was made with the initial application for registration or amendment; and
   - some of the data initially used to support the registration may have been determined to be unacceptable and may have been replaced. As a result, if additional data are required to support the proposed amendment to the registration, the entire product including the proposed amendment is subject to the data compensation requirements of section 3(c)(1)(F) of FIFRA.

5. **If an applicant obtains a letter from a company on the Data Submitters List** <https://epa.gov/pesticide-registration/pesticide-data-submitters-list-pdsl> **indicating that the company does not want any compensation for its data, may the applicant use this letter to demonstrate that the company has granted permission to use its data? What is necessary to comply with the permission required for the use of exclusive-use data?**

   The contents of a letter of authorization are described in 40 CFR 152.93(b)(1). Only in the case of exclusive use is explicit permission required. Otherwise, if the applicant goes through the proper data compensation procedures, permission from the data submitter is not required.

6. **If an applicant has a letter from a data submitter in its files granting the applicant permission to use the data submitter's data, can the applicant use the letter to support its application without getting new authorization to use the same data?**

   EPA will allow an applicant to use such a letter to certify that it has received written permission from the data submitter to cite its data, provided the letter of authorization is sufficiently clear that it extends to the use of the data to support the action in question.

   The Agency will honor the terms and conditions of an original letter of authorization to cite data and will not accept a letter withdrawing that authorization unless both the original data submitter and the applicant relying on the data submitter's data agree that such authorization has been withdrawn.

AR0000536

7. **If an applicant has a product that contains multiple active ingredients, some of which are purchased from registered sources and others that are not, can they claim a formulators' exemption for those active ingredients that are purchased from a registered source?**

   Yes, within the limits prescribed in 3(c)(2)(D) and 40 CFR 152.85, EPA will allow the formulators' exemption for the registered active ingredients if the use patterns on the applicant's label are supported by the applicant's registered source. Applicants should submit a properly completed Formulator's Exemption Statement (EPA Form 8570-27 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>).

8. **If the Cite-All Method of Support is used, does the applicant also have to submit a list of data requirements and references?**

   The cite-all method does not require an accompanying list of data requirements such as that required for the selective method; however, the Data Matrix (EPA Form 8570-35) must be submitted under the cite-all method to indicate the companies to whom offers of compensation were made.

9. **What is the specific timeframe by which a data submitter must respond to an applicant's offer to pay for data compensation, and if a data submitter does not respond, is the applicant still liable to pay for data compensation?**

   FIFRA and the regulations in 40 CFR Part 152, Subpart D do not require a data submitter to respond to offers within a specific timeframe to preserve data compensation rights. A data submitter may seek compensation at any time. Generally, the offer is made and negotiation commences shortly thereafter concerning the amount of compensation and the timing of payment.

10. **If an applicant writes to a company on the Data Submitters' List via certified mail and the letter is returned with an indication that the data submitter's company cannot be located, what else is required to find the company?**

    If the applicant has obtained a certified or registered mail statement that there is no known address for the data submitter's company, then the applicant has made a reasonable effort to notify that company. Of course, the applicant may pursue the matter further if so desired. Under these circumstances, the applicant should indicate in the application the actions undertaken to locate the data submitter. This documentation would be especially useful should a data submitter wish to challenge a registration in the future based on the applicant's failure to make an offer of compensation.

11. **If eligible for the formulators' exemption, does an applicant have to submit anything else in addition to the Formulator's Exemption Statement (EPA Form 8570- 27** <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>**) and the Confidential Statement of Formula (EPA Form 8570-4** <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>**)?**

    Unless the product is a 100% repack, i.e., the registered product purchased from another producer has only been repackaged or placed in a different container with no changes to the formulation, an applicant must submit information required for either the Selective or the Cite All Method of Support in addition to submitting the Formulator's Exemption Statement and Confidential Statement of Formula.

12. **Do applicants have to get permission from, or make an offer to pay, the person whose study appears in the public literature in order to cite that literature?**

    No, there is no such requirement. Under 40 CFR 152.94(b), submission of a public literature study or government-generated study does not confer any rights on the data submitter to exclusive use of data or compensation.

13. **If a study is jointly developed with government and private funds, are there circumstances when the private component may be subject to data compensation?**

    Yes. Provided the data are submitted by an applicant or registrant to support or maintain the registration of a pesticide, the private portion of the data development effort is subject to compensation, even when there may have been some measure of government involvement in the generation or funding of the data. EPA expects that the data submitter and the follow-on applicant will, through negotiation (or arbitration, should negotiations fail), determine the portion of the data development activity that was supported by private funds and therefore subject to compensation. It is important to note, however, that when EPA receives data directly from a government agency rather than from an applicant or registrant, it will presume these data to be entirely government-generated data under 40 CFR 152.94(b), and therefore "public literature" within the meaning of FIFRA section 3(c)(1)(F) that may be freely cited. Thus if applicants wish to receive compensation for data that may have been jointly developed with a government agency, the data must be submitted to EPA by the applicant or registrant.

    While compensation rights may apply to government-generated studies, exclusive use rights do not extend to these studies. EPA believes it would be inconsistent with the intent of Congress in enacting FIFRA to provide exclusive use treatment for data that have been generated or funded to some extent by the government. Since exclusive use rights, unlike compensation rights, are not segregable, rewarding such data with exclusive use treatment would be contrary to the direction in FIFRA that allows public literature to be cited freely.

AR0000538

Contacts for Additional Information

For assistance concerning the data compensation procedures, please contact the appropriate Branch for your pesticide product. Refer to Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

References Cited in Chapter 10

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the sources of these documents.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide registration and classification procedures
- Part 156 - Labeling Requirements for Pesticides and Devices
- Part 158 - Data Requirements for Registration
- Part 161 - Data Requirements for Registration of Antimicrobial Pesticides

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 3(c)(1)(F)
- Section 3(c)(2)(B)
- Section 3(c)(5)
- Section 3(c)(7)

PR Notices

- PR Notice 94-1 <https://epa.gov/pesticide-registration/prn-94-1-withdrawal-pr-notice-91-8> Withdrawal of PR Notice 91-8
- PR Notice 98-5 <https://epa.gov/pesticide-registration/prn-98-5-new-forms-certification-respect-citation-data> New forms for the Certification with Respect to Citation of Data

Data Submitters List <https://epa.gov/pesticide-registration/pesticide-data-submitters-list-pdsl>

AR0000539

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON NOVEMBER 2, 2022


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 11 – Tolerance Petitions

In this chapter:

- Tolerances and Exemptions from Tolerances
- Pesticide Tolerances
  - New Pesticide Registrations and Amendments to Existing Registrations
  - Temporary Tolerances for Experimental Use Permits
  - Tolerances for Use of Pesticides Under an Emergency Exemption
  - Import Tolerances
  - Tolerance-Setting Requirements for Inert Ingredients
  - Adjuvants
  - Antimicrobials
- Filing a Petition
  - Completing the Application
  - Registration or Amendment under FIFRA Section 3
  - Fee Requirements
- References Cited in Chapter 11

Tolerances and Exemptions from Tolerances

This chapter provides information on definitions, interpretative regulations and procedures for filing a petition for establishment of a tolerance or an exemption from the requirement of a tolerance. Read more about tolerances <https://epa.gov/pesticide-tolerances/about-pesticide-tolerances>.

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>, EPA is responsible for regulating the amount of pesticide residues that can remain in or on food or feed commodities as the result of a pesticide application. A tolerance is the maximum residue level of a pesticide (usually measured in parts per million, or ppm) that legally can be present in food or feed.

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. **Tolerance Petitions**
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- If residues of a pesticide exceed the established tolerance, or no tolerance has been established, the crop is considered adulterated and may be seized by the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), or a state enforcement agency.

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by, among other things, consolidating EPA's authority for establishing, modifying, and revoking pesticide tolerances under FFDCA section 408. EPA no longer establishes tolerances for pesticides in processed food/feed commodities under FFDCA section 409. Now all tolerances for raw agricultural commodities (RACs) and processed food/feed commodities (if required) are established under FFDCA section 408. Subsequently, the Antimicrobial Regulation Technical Corrections Act (ARTCA) of 1998 amended the FFDCA <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> by excluding certain antimicrobial pesticides from FFDCA section 408. Tolerances for residues of those pesticides are set by FDA under FFDCA section 409.

- As EPA amends or renews tolerances in accordance with FQPA, the Agency will issue those amendments and renewals in 40 CFR Part 180.

Pesticide Tolerances

Foods in interstate commerce containing pesticide residues must be covered by pesticide tolerances. Pesticide residues may result from:

- direct treatment of target crop or treatment to seed stock with a pesticide (whether that treatment occurs in the United States or a foreign country);
- use of antimicrobial pesticides in food processing (under ARTCA, tolerances for many antimicrobial uses are set by FDA under FFDCA section 409);
- inadvertent carryover of residues in the soil to rotational or replacement crops;
- runoff and spray drift;
- consumption of treated commodities by livestock (including primary or secondary residues in meat, milk, poultry, and eggs); and
- post-harvest applications.

Tolerances for residues in raw commodities apply to those same residues in processed commodities. If the residues in processed commodities may exceed the residues in the raw commodity, a separate processed food tolerance is needed.

Registration of a pesticide is not, however, a prerequisite for establishing a tolerance. For example, EPA may establish a temporary tolerance under FFDCA section 408(r) <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> to permit the experimental use of a non-registered pesticide, or EPA may establish a tolerance for a pesticide residue resulting from the use of the pesticide in food or feed production in a foreign country <https://epa.gov/pesticide-tolerances/nafta-guidance-data-requirements-pesticide-import-tolerances-questions-answers>.

New Pesticide Registrations and Amendments to Existing Registrations

A tolerance or the exemption from the requirement of a tolerance must be established for each active and inert ingredient in the formulation before a pesticide can be registered for use on a food or feed crop, or for use in a food processing or storage area. In addition, an amendment to an established tolerance may be required if an amendment is proposed for a currently registered use that might result in residue levels higher than the established tolerance. Examples include an increase in the dosage rates and/or an increase in the frequency of application. To enable the Agency to establish or amend a tolerance or tolerance exemption, a tolerance petition needs be submitted.

Temporary Tolerances for Experimental Use Permits

An applicant must obtain a temporary tolerance or exemption from the requirement of a tolerance to accompany an experimental use permit (EUP) for uses that have not been registered if the crop(s) treated during the EUP is (are) not destroyed or otherwise prevented from entering food or feed in interstate commerce

Under FFDCA section 408(r) <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>, EPA may establish a temporary tolerance or exemption from the requirement of a tolerance on its own initiative or at the request of any person who holds an EUP. A temporary tolerance allows participants in the EUP program to market or use commodities harvested from the EUP test plots.

- The petition for the temporary tolerance must be submitted with the application for the experimental use permit (Chapter 12 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>).

Tolerances for Use of Pesticides Under an Emergency Exemption

A time-limited tolerance or exemption from the requirement must be established for pesticides approved for use on food or feed crops under emergency exemptions according to FIFRA section 18 <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>).

Import Tolerances

Residues of a pesticide not registered for use in the United States may be present in raw agricultural commodities (RACs) and processed foods produced abroad and imported into this country if a tolerance has been established for those residues and the residues are within the tolerance.

AR0000549

> - Under FFDCA section 408 <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>, these imported commodities are considered adulterated unless the Agency has established a tolerance for the pesticide on that commodity and the residues are within the tolerance.

The requirements of section 408 of the FFDCA apply equally to domestically produced and imported food and feed found to contain pesticide residues. Therefore, even though the use of a pesticide in a foreign country is not subject to EPA registration requirements under FIFRA, a pesticide residue in imported food or feed must conform with a tolerance or tolerance exemption established by EPA.

Shipments of imported food/feed items found to have pesticide residues for which a tolerance or exemption from the requirement of a tolerance has not been issued will be held up and the importer required to:

> 1. file for a tolerance or exemption from a tolerance;
> 2. return the shipment to the country of origin; or
> 3. destroy the shipment.

Registrants who wish to submit an import tolerance petition under NAFTA (North American Free Trade Agreement) should refer to the NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada (December 2005) <https://epa.gov/pesticide-tolerances/nafta-guidance-document-data-requirements-tolerances-imported-commodities> announced in the Federal Register on April 5, 2006 (71 FR 17099). This document finalized the requirements originally proposed in the *Federal Register* on April 16, 2003 (68 FR 18638). For more information, see the "Questions and Answers at the NAFTA Guidance on Data Requirements for Pesticide Import Tolerances" <https://epa.gov/pesticide-tolerances/nafta-guidance-data-requirements-pesticide-import-tolerances-questions-answers> Web page developed by EPA.

Tolerance-Setting Requirements for Inert Ingredients

Inert ingredients in pesticide product formulations are regulated under both FIFRA and FFDCA (Chapter 8 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>).

Inert ingredients in products labeled for food use must have a tolerance or exemption from tolerance before the product can be registered. Under the FFDCA, both the active and inert ingredients in a pesticide need a tolerance or an exemption from tolerance. Further, regulations found in 40 CFR 152.50(i) require that inert ingredients, as well as active ingredients, in a pesticide product must have all needed tolerances or exemptions for tolerances before the pesticide can be registered under FIFRA. A statement must be submitted indicating whether a tolerance or exemption from the requirement of a tolerance has been issued by the Agency under section 408 of FFDCA if the proposed labeling bears instructions for use of the product on food or feed crops or if the intended use of the product may result directly or indirectly in pesticide residues in or on food or feed.

If a tolerance or exemption from the requirement of a tolerance has not been issued for such residues, an application must be accompanied by a petition for establishment of appropriate tolerances or exemptions from the requirement of a tolerance in accordance with 40 CFR Part 180 (tolerance or exemption petitions).

AR0000550

- EPA will not register a pesticide product for food/feed uses unless all of the inert ingredients in the product have been approved for use under the FFDCA on food/feed items.
- Refer to 40 CFR 180.910 – 180.960 for a listing of the inert ingredients that have been approved for use under the FFDCA on food/feed items.

Adjuvants

If the use of an adjuvant may result in detectable residues on food, the applicant should contact the EPA product manager or registration ombudsman (Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>) prior to submitting the application to discuss the potential need for a tolerance.

Antimicrobials

EPA has jurisdiction for certain food contact sanitizing solutions under FIFRA and FFDCA section 408. Permitted active and inert components of food contact sanitizing solutions are found in 40 CFR 180.940, 180.950 and 180.960.

Filing a Petition

Procedures for filing a petition requesting the establishment or amendment of a tolerance, a temporary tolerance, an exemption from the requirement of a tolerance, or a temporary exemption from a tolerance are described in detail in 40 CFR 180.7 and below in the section titled "Completing the Application".

Additional information concerning requests for temporary tolerances, or a temporary exemption from a tolerance in conjunction with an experimental use permit, can be found in 40 CFR 180.31.

There is no application form for petitions. Requests must contain the information listed in 40 CFR 180.7. Please refer to PR Notice 97-1 <https://epa.gov/pesticide-registration/prn-97-1-agency-actions-under-requirements-food-quality-protection-act> for information on filing a tolerance petition under FQPA. General information on the format recommended by the Agency to submit this information is provided below.

Completing the Application

In order to assure expeditious processing, the petition should present the information required in 40 CFR 180.7 in the following format:

Summary

The Federal Food, Drug and Cosmetic Act requires that the petitioner submit an informative summary of the petition and the data, and any other information and arguments submitted or cited in support of the petition (40 CFR 180.7(b)(1) and (2)). Both a paper and electronic copy of the summary should be submitted. The electronic copy should be formatted according to OPP's current standard for electronic data submission <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications> and the Notice of Filing <https://epa.gov/pesticide-registration/pesticide-registration-manual-registrant-summary-pesticide-petitions-epas>. The petition must include a statement that the petitioner agrees that such summary and any information it contains may be published as part of the notice of filing of the petition to be published under FFDCA section 408(d)(3) and as part of a proposed or final regulation issued under FFDCA section 408. The Agency will use this

summary to provide the public with information concerning the petition. The summary will be included in the EPA's electronic public docket, and the Notice of Filing of the petition published in the Federal Register will refer interested parties to the summary in the docket.

Section A

Include the name, chemical identity, and composition of the pesticide chemical (40 CFR 180.7(b)(3)). For EPA to assess the composition of the pesticide, information is required on the manufacturing process, chemical analysis of the active ingredient, certified limits for ingredients of a product, and analytical methods to determine the composition of the pesticide. Please refer to 40 CFR 158.300 - 158.355 and Product Chemistry Data Requirements and OPPTS Harmonized Guidelines Series 830 <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic> for more detailed information.

Applicants are encouraged to use the study profile templates in developing their manufacturing and chemical analysis study documents. These templates provide a summary of the study that if submitted electronically with the study report, can be used by the Agency to efficiently develop its own review of the study and may be found by going to the Study Profile Templates <https://epa.gov/pesticide-registration/study-profile-templates> Web page.

Important Note: EPA evaluates the composition data to determine whether impurities could constitute a significant component of the residues in food and feed commodities. Impurities that arise in the manufacture of pesticides can become a residue problem if they are not identified before tolerances are established. Dioxins and nitrosamines are the best-known examples of significant impurities of toxicological concern. If impurities are at levels that may lead to toxicologically significant residues in crops or the environment, then adjustments to the manufacturing process or additional purification steps will be necessary to reduce the impurities to a safe level. Refer to PR Notice 96-8 <https://epa.gov/pesticide-registration/prn-96-8-toxicologically-significant-levels-pesticide-active-ingredients>.

Section B

Indicate the amount, frequency, and timing of application of the pesticide chemical (40 CFR 180.7(b)(4)). This refers to the directions for use, dosage rates, number of applications, restrictions, pre-harvest intervals, and times of application proposed for inclusion on the label of the product to be marketed.

Section C

Include the full reports on investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting the tests and investigations (40 CFR 180.7(b)(5)). Refer to 40 CFR 158.500, Toxicology Data Requirements (for antimicrobial pesticides,40 CFR 161.340) and OPPTS Harmonized Guidelines, Series 870 <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic>, for the types of toxicity data that are needed to support a petition request. The required data are identified under the "Food Crop" headings. Include in this section such information that may be required on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects (40 CFR 180.7(b)(12)) and information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue (40 CFR 180.7(b)(13).

Applicants are encouraged to use the study profile templates in developing their toxicity study documents. These templates provide a summary of the study that if submitted electronically with the study report, can be used by the Agency to efficiently develop its own review of the study and may be found by going to the Study Profile Templates <https://epa.gov/pesticide-registration/study-profile-templates> Web page.

Section D

Include the results of tests on the amount of residue remaining, including a description of the analytical method used (40 CFR 180.7(b)(6) and 40 CFR 180.7(b)(10)). Information on testing for the amount of residue remaining in the raw agricultural commodity or processed food or feed, when the pesticide is applied according to the proposed label directions, is provided in 40 CFR 180.34 *Tests on the amount of residue remaining*, 40 CFR 158.1400 (for antimicrobial pesticides, 40 CFR 161.240), *Residue Chemistry Data Requirements*, and the OPPTS Harmonized Guidelines, Series 860 <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic>.

Applicants are encouraged to use the study profile templates in developing their residues and analytical methods study documents. These templates provide a summary of the study that if submitted electronically with the study report, can be used by the Agency to efficiently develop its own review of the study and may be found by going to the Study Profile Templates <https://epa.gov/pesticide-registration/study-profile-templates> Web page.

Submitting Analytical Methods for Use in Tolerance Enforcement

Applicants will need to develop and submit accurate and precise analytical methods for identifying and measuring the amount of pesticide residues in the agricultural commodity and processed foods (40 CFR 180.7(b)(9)).

Those methods need to be practical in order to be used in tolerance enforcement and should meet all of the specifications for pesticide residue methods identified in the Residue Chemistry Test Guidelines, OPPTS Series 860 <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic>.

- The enforcement analytical method cannot be claimed Confidential or Trade Secret.

In addition, petitioners should submit pesticide validation data showing the results from their own (or a contract) laboratory, as well as the results from an additional independent laboratory that confirms those results. Further, it is recommended that tandem-stage MS (e.g., LC-MS/MS or GC-MS/MS) methods monitor two ion transitions to include both identification and confirmation of that identification, as this is the generally recognized standard for regulatory monitoring.

The exact procedure for conducting an independent laboratory validation (ILV) can be found in OPPTS Harmonized Guidelines, Series 860, Guideline 860.1340 <https://epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic> and PR Notice 96-1 <https://epa.gov/pesticide-registration/prn-96-1-tolerance-enforcement-methods-independent-laboratory-validation>. Additional information can be found in the Residue Analytical Methods Index <https://epa.gov/pesticide-analytical-methods/analytical-methods-measuring-pesticide-residues>.

Section E

This section details the practical methods for removing residues that exceed any proposed tolerance (40 CFR 180.7(b)(8)). Tolerances are usually set at levels that are adequate to cover residues that are likely to result from a proposed use without any special processing of the commodities to reduce residues to the tolerance level.

Section F

This section includes proposed tolerances for the pesticide chemical (40 CFR 180.7(b)(7). Tolerances should be proposed in terms that best represent the total residues on the raw agricultural commodity, whether it be the parent pesticide, altered forms of it, or both.

An exemption from the requirement of a tolerance may be proposed when appropriate.

> - According to 40 CFR 180.900, an exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to human health.

When an exemption is proposed, data may be necessary to show the level of residues expected.

This section also includes information concerning any maximum residue level established by the Codex Alimentarius Commission for the pesticide chemical residue addressed in the petition. If a Codex maximum residue level has been established for the pesticide chemical residue and the petitioner does not propose that this level be adopted, a statement explaining the reasons for this departure from the Codex level (40 CFR 180.7(b)(14) should be provided.

Section G

This section presents the reasonable grounds in support of the petition. Such reasons should include a rationale of how the residue data support the proposed tolerance, brief discussions on the adequacy of the analytical method with respect to sensitivity and determination of total toxic residues, an explanation of any aberrant residue values reported, an explanation for the omission or substitution of required data or information, discussion of the fate of the pesticide in the environment (i.e., soil persistence, contamination of groundwater or runoff water), and any residue considerations applicable to the proposed use. In addition, a summary of the grounds for safety of the proposed tolerance, based on the toxicology data submitted under Section C, may also be included.

Important Note: If EPA does not receive all of the items identified above listed in 40 CFR 180.7, the petition and application will be rejected at the end of the 21-day initial content screen under PRIA as described in Chapter 5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>. Petitioners are encouraged to contact their registration ombudsman with any questions on required testing or formatting prior to submitting an application or petition.

Supporting Data

Three copies of any data required in support of the petition must be submitted in accordance with the data formatting requirements set forth in PR Notice 86-5 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>.

Registration or Amendment under FIFRA Section 3

Except in certain instances, a petition request must be accompanied by an application for registration, an application to amend the registration of a currently registered product, or an experimental use permit for the uses proposed in the petition. A request for an import tolerance generally would not require an accompanying application for registration.

Fee Requirements

Refer to Chapter 5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees> for detailed information on the Pesticide Registration Improvement Act of 2003 (PRIA) <https://epa.gov/pria-fees>, which was reauthorized by the Pesticide Registration Improvement Extension Act of 2012 <https://epa.gov/pria-fees> and how this

legislation has created a registration service fee system for specific pesticide registration, amended registration, and tolerance-setting actions.

Fees are assessed for specific EPA review actions for conventional chemical pesticide products, antimicrobial products, and biopesticide products. In return, EPA is obligated to perform certain review functions and make regulatory determinations within a specific timeframe.

Please contact the appropriate Ombudsman for the type of pesticide product (or new active ingredients) or, alternatively, the Product Manager or Branch Chief (Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>) responsible for the pesticide (for existing active ingredients) for questions concerning:

- whether a petition for a tolerance is required;
- the appropriate fee;
- how to submit a request for a petition for a tolerance and/or application for product registration; or
- what data are required to support a petition for tolerance and/or application for product registration.

If the petition request involves a new chemical not yet assigned, then the inquiry should be directed to the Ombudsman.

References Cited in Chapter 11

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

Code of Federal Regulation, Title 40

- Part 158 - Data Requirements for Registration
- Part 161 – Data Requirements for Registration of Antimicrobial Pesticides (Currently being revised, refer to last proposed revision in the Federal Register of March 11, 2005 (70 FR 12276 <https://www.govinfo.gov/content/pkg/fr-2005-03-11/pdf/05-4873.pdf>)
- Part 180 - Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Foods

Code of Federal Regulation, Title 21

- Part 178 –Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

Federal Food, Drug and Cosmetic Act <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>

- Section 408 – Tolerances and Exemptions for Pesticide Chemical Residues

OPPTS Harmonized Test Guidelines <https://epa.gov/test-guidelines-pesticides-and-toxic-substances>

- 830 Series - Product Properties Test Guidelines
- 860 Series - Residue Chemistry Test Guidelines
- 870 Series - Health Effects Test Guidelines

Federal Register Notices

- NAFTA Guidance Document on Requirements for Tolerances on Imported Commodities in the U.S. and Canada: Notice of Availability (PDF) <https://www.govinfo.gov/content/pkg/fr-2006-04-05/pdf/e6-4948.pdf> (1 pp, 139 K, About PDF <https://epa.gov/home/pdf-files>), April 5, 2006 (71 FR 17099).
- Inert Ingredient Tolerances (PDF) <https://www.govinfo.gov/content/pkg/fr-2000-07-24/pdf/00-18646.pdf> (6 pp, 234 K, About PDF <https://epa.gov/home/pdf-files>), July 24, 2000 (65 FR 45569)

NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada (December 2005) <https://epa.gov/pesticide-tolerances/nafta-guidance-document-data-requirements-tolerances-imported-commodities> dated December 2005

PR Notices

AR0000556

- PR Notice 86-5 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions> - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)
- PR Notice 96-1 <https://epa.gov/pesticide-registration/prn-96-1-tolerance-enforcement-methods-independent-laboratory-validation> -Tolerance Enforcement Methods – Independent Laboratory Validation by Petitioner
- PR Notice 96-8 <https://epa.gov/pesticide-registration/prn-96-8-toxicologically-significant-levels-pesticide-active-ingredients> – Toxicologically Significant Levels of Pesticide Active Ingredients
- PR Notice 97-1 <https://epa.gov/pesticide-registration/prn-97-1-agency-actions-under-requirements-food-quality-protection-act> - Agency Actions under the Requirements of the Food Quality Protection Act

Antimicrobial Regulation Technical Corrections Act of 1998 <http://www.fda.gov/ohrms/dockets/98fr/081399a.txt> amending FFDCA

Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities <https://epa.gov/pesticide-tolerances/indexes-part-180-tolerance-information-pesticide-chemicals-food-and-feed>

Pesticides and Food: What the Pesticide Residue Limits are on Food <https://epa.gov/pesticide-tolerances>

Food and Feed Commodity Vocabulary <https://epa.gov/pesticide-tolerances/food-and-feed-commodity-vocabulary>

Pesticide Registration Home <https://epa.gov/pesticide-registration>
About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>
Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>
Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>
Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>
Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>
— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>
— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>
— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>
— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>
Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>
— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>
— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 12 – Applying for an Experimental Use Permit

In this chapter:

- Introduction to Experimental Use Permits
- Requirements for an Experimental Use Permit
- Exemptions from EUP Requirements
- EUPs for Indoor and Certain Antimicrobial Uses
- EUPs for Small-Scale Field Testing of Microbial Pesticides
- Applying for an EUP
  - Information Required in All EUP Applications
  - Information Required When the Product to be Tested is Not Already Registered
  - When Testing May Result in Pesticide Residues on Food
  - Labeling Requirements
  - Fee Requirements
  - Suggested Format for an Experimental Use Permit Application
- Extensions or Renewal of Experimental Use Permits
- Program Surveillance and Data Reporting Requirements for an Experimental Use Permit
- References Cited in Chapter 12

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Introduction to Experimental Use Permits

This chapter describes the requirements for Experimental Use Permits (EUPs) and includes how to apply for an EUP, labeling requirements, application format, and data reporting requirements.

EPA requires that a pesticide product undergo extensive chemical, toxicological, and field-testing before being registered as a pesticide. Some testing is done under field conditions using commercial application equipment to fully understand the pesticide's chemical properties, safety, and efficacy.

Because testing undertaken as part of the registration process necessarily involves an unregistered product or is for a use not previously approved in the registration of the pesticide, EPA sometimes must first authorize the distribution and sale for testing purposes by means of an experimental use permit (EUP) under FIFRA section 5 <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>.

The EUP establishes limited conditions for the transportation, application, and disposal of the pesticide material used in the tests. Pesticides registered under an EUP may not be sold or distributed other than through approved participants in the test program, and use is limited to the conditions specified in the EUP. Please refer to 40 CFR Part 172 for detailed information on EUPs.

Requirements for an Experimental Use Permit

A first step for the applicant is to determine whether an EUP is required for the particular testing being considered. If the product is not intended to be used as a pesticide, an EUP would not be needed to test the product. Additionally, certain pesticide testing operations may not require an EUP if the criteria of 40 CFR 172.3 are met, as discussed below.

In general, EUPs are issued for:

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. **Applying for an Experimental Use Permit**
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- pesticides containing any chemical or combination of chemicals that have not been included in any previously registered pesticide; and
- registered pesticides for which a use, e.g., application to a particular crop, is not registered with the Agency.

However, there are certain tests and circumstances that are exempt from the requirements of an EUP because they are presumed not to involve unreasonable adverse effects. These exemptions are summarized below and described in detail in 40 CFR 172.3(b) and (c).

Exemptions from EUP Requirements

EPA generally will not require an EUP for a substance or mixture of substances if the EUP is limited to:

AR0000566

- **Laboratory or Greenhouse Tests**
- **Limited Replicated Field Trials** involving fewer than 10 acres per pest for terrestrial tests or less than one acre per pest for aquatic tests, in which the sole purpose is to determine pesticidal value, toxicity, or other properties under the following small-scale field testing scenarios:
  - **Land** - Pesticide testing on plots of land 10 acres or less in size. Specifically, test plots may be as large as 10 acres per pest if the effect of each pesticide on several pests is being investigated at a different time for each pest. However, if pesticide effects on more than one pest are being investigated all at the same time, the test plot may not exceed 10 acres in size. Furthermore, any food or feed crops involved in or affected by the tests must be destroyed or consumed only by experimental animals unless a tolerance or exemption from a tolerance has been established. Please refer to 40 CFR 172.3(c)(1).
  - **Aquatic Uses** - Pesticide testing on water bodies one surface acre or less in size. Specifically, water bodies may be as large as one acre per pest if the effect of each pesticide on several pests is being investigated at a different time for each pest. However, if pesticide effects on more than one pest are being investigated all at the same time, the water body may not exceed one acre in size.
    - Bodies of water involved in or affected by the tests may not be used for irrigation, drinking water supplies, or body contact through recreational activities. In addition, pesticides may not be tested in waters that contain or that affect any fish, shellfish, or other plants or animals that may be taken for food or feed unless a tolerance or exemption from tolerance exists for the test product. Please refer to 40 CFR 172.3(c)(2).
- **Animal Treatment Uses** - Tests may be conducted only in cases where experimental animals will not be used for food or feed unless a tolerance or exemption from tolerance exists for the test product. Please refer to 40 CFR 172.3(c)(3).
- **Other Uses** - For testing operations for which acreage limits do not accurately reflect whether the testing is to be considered small- or large-scale, the Agency will determine on a case-by-case basis whether an exemption from the requirement of an EUP is appropriate. Applicants should consult with the appropriate regulatory division in OPP before initiating such testing.

The exemptions described above are not definitive. 40 CFR 172.3 gives EPA discretionary authority to exempt particular testing operations from the EUP requirements under other conditions, as well as allowing EPA discretionary authority to require EUPs for testing operations even when the exemption conditions of 40 CFR 172.3(b) and (c) are met.

Important Note: EUPs are required for testing of pesticides indoors, as well as in outdoor agricultural settings. This includes testing pesticides to control roaches in domestic dwellings and institutions, and for field-testing of swimming pool sanitizers and disinfectants under actual use conditions.

EUPs for Nonagricultural and Certain Antimicrobial Uses

EUPs are generally required for testing of pesticides indoors, some non-agricultural uses as well as in outdoor agricultural settings. This includes testing pesticides to control roaches and other insects in domestic dwellings and institutions, control termites in and around structures and buildings, control invasive species, and control birds and animals. EPA will determine on a case-by-case basis when an EUP will be required in these situations in accordance with 40 CFR 172.3(e). Applicants should contact the appropriate registration ombudsman <https://epa.gov/pesticide-contacts/contacting-epa-about-regulating-pesticides-issues> who will consult with appropriate staff to determine whether an EUP will be required.

EUPS are required for field-testing of swimming pool sanitizers and disinfectants under actual use conditions. 40 CFR 172.3(c)(2) states that an EUP is not required for a small scale test conducted on a cumulative total of no more than one surface acre of water per pest with several exceptions including that the treated body of water cannot be used for irrigation, drinking water supplies, or body contact through recreational activities. However, a swimming pool disinfection/sanitization use requires an EUP because the efficacy testing required to support the use involves in-use field testing in at least two swimming pools.

There are numerous factors that influence the concentrations necessary for disinfection of swimming pool water in practical applications such as the numbers of swimmers in the pool, frequency of use, frequency with which water is changed, general weather conditions, types and degree of organic contamination of the water by the swimmers themselves (e.g., suntan lotions and oils) and other types of debris. These factors need to be considered when evaluating the effectiveness of a swimming pool sanitizer or disinfectant.

Thus, the efficacy data required to support a swimming pool disinfection/sanitization use consists of a two-phased study (laboratory testing and field testing). The EUP application should include an efficacy protocol that describes in detail all tests and step-by-step procedures that are proposed for the in-use swimming pool field tests. Guidance for field testing water that the public may come into contact with through recreational activities such as swimming in pools and spas, is located in the Pesticide Assessment Guidelines Subdivision G, Section 91-8(c) .

EUPs for Small-Scale Field Testing of Microbial Pesticides

Because of concern about the potential for microorganisms to reproduce and multiply in the environment and the potential for these microbials to cause unforeseen adverse impacts, the Agency may require an EUP for small-scale field-testing of certain microbial pesticides (i.e., genetically altered and nonindigenous microbial pest control agents).

Before the initiation of certain small scale testing involving genetically altered or nonindigenous microbial pest control agents, the research organization, company, or individual must submit a notification to EPA so a determination can be made as to whether an EUP is required. 40 CFR 172.43-59 presents the requirements for an EUP for field-testing of microbial pesticides. Note that these differ significantly from the EUP requirements for testing other pesticides.

Applicants should also refer to Chapter 3 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations> of this document for a more detailed discussion of the Agency's policy and requirements for small-scale field-testing for microbial pesticides.

AR0000568

Applying for an EUP

An application for an EUP may be submitted by any company or person wishing to generate information necessary to register a product under FIFRA as per 40 CFR 172.2(a). The applicant may be a potential registrant, an independent researcher or testing laboratory, or any similar agent or consultant of a manufacturer. Applications must be submitted to the appropriate address given in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>.

EPA Form 8570-17, Application for Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, must be submitted to EPA with each EUP application. The type of information to be submitted with the application depends on whether the product is already registered and whether a tolerance is required for the testing covered under the EUP. 40 CFR 172.4 lists the information required in each case.

Information Required in All EUP Applications

Each EUP application must contain the following information together with a completed copy of EPA Form 8570-17 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>, *Application for Experimental Use Permit*, and five copies of the proposed labeling (refer to the Labeling Requirements section of this chapter):

AR0000569

- applicant's name and address;
- the registration number of the product, if it has been registered (Information requirements for unregistered products are listed below in a separate section);
- purpose or objectives of the proposed testing;
- detailed description of the proposed testing program including the following test parameters:
  - pest organism(s) involved;
  - amount of pesticide proposed to be used;
  - crops, fauna, and flora involved;
  - sites and modes of pesticide applications;
  - pesticide dosage rates;
  - location of test site, including states;
  - number of acres in test site;
  - number of structural sites or number of animals by state to be included in the testing;
  - proposed dates of the testing;
  - how the testing will be supervised;
  - name, street address, telephone number and qualifications of program participants, including those not employed by the applicant;
  - names and street addresses of cooperators (persons owning or controlling application sites and granting permission to permittees to use these sites), if available at the time of the application or as soon thereafter as available;
  - results of prior testing of product by applicant to determine:
    - toxicity and effects in or on target organisms;
    - toxicity and effects in or on nontarget plants, animals and insects at or near the application site;
    - harm to the environment from application of this product; and
  - how the applicant intends to store and dispose of unused pesticide and containers from the proposed experimental use.

Information Required When the Product to be Tested is Not Already Registered

In addition to the information listed immediately above, when the product to be tested has not been registered, the applicant must provide the following information:

AR0000570

- a complete confidential statement of formula of the product to be tested that provides a tabulation of the names and percentage by weight of each ingredient, both active and inert (EPA Form 8570-4 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>), Confidential Statement of Formula)
- chemical and physical properties of each active ingredient of the formulation being tested, including the analytical methods to be used to determine these (40 CFR 158.210, 158.220, 40 CFR 158.310, 40 CFR 158.2081, 40 CFR 158.2171 and 40 CFR 161.150-161.190);
- available data on the rate of decline of residues on the treated crop or site together with other information relevant to determining when workers can safely re-enter treated areas (40 CFR 158.250, 40 CFR 158.270, 40 CFR 2082, 40 CFR 158.2172, 40 CFR 161.240 and 40 CFR 161.390);
- available toxicity and exposure data, including human epidemiological data, relevant to assessing the potential of the product to cause injury to users and other people who may be exposed (40 CFR 158.230, 40 CFR 158.240, 40 CFR 158.243, 40 158.260, 40 CFR 158.2083, 40 CFR 158.2084, 40 CFR 158.2173, 40 CFR 158.2174 and 40 CFR 161.340).
- submitted data (three copies) should be bound and formatted in accordance with the requirements of PR Notice 86-5 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>.

When Testing May Result in Pesticide Residues on Food

When the product to be tested is to be used in such a manner as to leave residue on food or feed, the applicant has three options regarding tolerances:

- The applicant may submit evidence that a tolerance or a tolerance requirement exemption has been established under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA).
- The applicant may submit a petition for a new tolerance or for an exemption from the requirement for a tolerance established under section 408 of FFDCA. Chapter 11 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions> of this document, Tolerance Petitions, describes this process in detail. Or
- The applicant may certify that the food or feed derived from the experimental program will be destroyed or will be fed only to experimental animals, which will be destroyed. Alternatively, the applicant may certify that the food or feed derived from the experimental program will be disposed of in another manner that does not endanger man or the environment. The permit application shall specify the means of such disposal.

Important Note: The Agency review process is greatly facilitated if applicants include a table indicating the states to which the product is to be shipped, the pounds of product to be shipped to each state for each pest or pest complex, and the total pounds of product to be shipped to each state. Also note that if the participants change, the permit needs to be modified (40 CFR 172.4(iv)).

Labeling Requirements

40 CFR 172.6 requires that all pesticides shipped or used under an experimental use permit must be labeled with directions and conditions for use, including the following:

- the prominent statement "For Experimental Use Only";
- the Experimental Use Permit Number;
- the statement "Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program";
- the name, brand, or trademark;
- the name and address of the permittee, producer, or registrant;
- the net contents;
- an ingredient statement;
- warning or caution statements;
- any limitations on entry of persons into treated areas;
- the establishment registration number, except in those cases where application of the pesticide is made solely by the producer; and
- the directions for trial use.

In the case of a registered pesticide, EPA may permit a pesticide to be used under an experimental use permit with approved supplemental labeling.

Note: Please refer to Chapter 2 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product> for more information on label and labeling formats.

Fee Requirements

Refer to Chapter 5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees> for detailed information on fees.

Based on legislative requirements, fees are assessed for specific EPA review actions for conventional chemical pesticides, antimicrobial products, and biological products. In return, EPA is obligated to perform certain review functions and make regulatory determinations within a specific timeframe.

Suggested Format for an Experimental Use Permit Application

The following format is an example of an acceptable EUP application. Please note that all of the items are not necessary in every case. Depending on whether the product being tested is already registered with EPA, and whether a tolerance is necessary because treated crops will be used as food or feed, several of these entries may not be necessary. See the

AR0000572

section earlier in this chapter entitled “Applying for an EUP” for an explanation of what information is required in each of these situations.

Section A

This section should include a data sheet detailing the chemical and physical properties of the test chemical along with a complete statement of the names and percentages by weight of each active and inert ingredient in the formulation to be shipped. The Confidential Statement of Formula, EPA Form 8570-4 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms> can be used for some of this information.

Section B

This section should include a copy of the proposed experimental label. The minimum labeling requirements are set forth in 40 CFR 172.6.

Section C

This section should include toxicity data, including oral and dermal LD50 values, inhalation LC50 values, and eye and skin irritation data for the formulated product, as well as subchronic toxicity, developmental toxicity (one species), mutagenicity, and potentially, chronic toxicity and reproduction data on the active ingredient. Data on the product’s toxicity to fish and wildlife may also be included in Section C, as appropriate (40 CFR Part 158) and for antimicrobial pesticides, 40 CFR Part 161).

Section D

This section should include residue data, including, when appropriate, data on: (1) food or feed commodities; (2) nonfood crops such as tobacco; or (3) foliage or other sites where the product may be used and on which remaining residues of the product may pose a risk to humans or the environment. Section D also includes a description of the analytical methods used, a summary of the residue data acquired, and when appropriate, environmental fate data.

Section E

This section should include product performance information demonstrating that the product is useful for the purposes proposed. Because EPA has waived the requirement for submitting efficacy data for all products except those with public health uses, Section E need not contain actual efficacy data, but should include a summary of the results of all efficacy testing performed on the product.

Section F

This section should include a statement explaining whether a tolerance exists or is being requested, especially if the product is to be tested in a manner that may result in residues in food or feed. If a tolerance is being requested, the temporary tolerance petition must be provided with the EUP application. Whenever all food or feed derived from the experimental program is to be destroyed or fed to experimental animals, a statement must be included explaining this.

Section G

The section should include details concerning the proposed experimental program, including:

AR0000573

- qualifications, names, addresses, and telephone numbers of all EUP participants, including cooperators, i.e., persons who grant permission for an experimental use pesticide to be used on application sites they own or control;
- names of states in which the product will be used, along with the amount of active ingredient and acreage (or other appropriate measures) to be used in each state, and the names of states in which the pesticide may be shipped for further distribution;
- details of the proposed EUP program:
  - types of pests or organisms targeted;
  - the crops, animals, surface, or sites to be treated;
  - the geographical areas where the material is to be used;
  - the use patterns, intended plot sizes, number of plots, number of replicates, and other test parameters to be used;
- information on prior testing:
  - description and the specific results of any appropriate prior testing of the product conducted by the applicant to determine toxicity and effects in or on any target organisms at the site of application,
  - phytotoxicity and other forms of toxicity or effects on nontarget plants, animals, and insects, at or near the site of application, or
  - adverse effects on the environment;
- objectives of the EUP program, including a statement specifying the type of data to be collected and the intended gain from conducting the program;
- justification for the quantity (volume) of active ingredient proposed to be used under the EUP, including a statement specifying the various parameters used to determine the quantity of active ingredient;
- a statement proposing a suitable duration for the EUP commensurate with the program objectives; and
- details concerning the method of disposing of unused materials at the conclusion of the testing program.

Extensions or Renewal of Experimental Use Permits

EUPs and associated temporary tolerances are usually issued for a period of one or two years. The permit and any associated temporary tolerances may be extended, renewed, or amended upon written request to the Agency, if circumstances warrant. The written request should include an explanation/justification for requesting the extension/renewal/amendment. Please note that the Agency processing time may, in certain circumstances, be similar to new EUPs. The applicant must request an amendment to an EUP if one or more of the following changes are requested:

- if the EUP was established as a crop destruct, but the applicant seeks to change it to a noncrop destruct;
- if the applicant seeks to reallocate acreage across states or add new states; and
- if the applicant intends to make EUP labeling change

Program Surveillance and Data Reporting Requirements for an Experimental Use Permit

Once the permit is issued and the pesticide testing is under way, the applicant is required to track the results at each test site and submit to EPA within 180 days after the expiration of the permit a final report that shall include (40 CFR 172.8):

- All data gathered during the testing program. Although field notes need not be included in this report, they must be kept available for EPA review upon request.
- A report of how pesticide containers and unused pesticides were disposed of, including the quantity disposed of, disposal sites, and disposal methods.
- The method of disposition of affected food and/or feed.
- In the case where meat-producing animals or birds are treated by or exposed to an experimental use pesticide, the applicant must report the name and location where the animals will be processed to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Washington, DC 20250.

EPA, as well as the state, may require advance notice from the applicant of the intended test dates, sites, and times. The applicant must also allow EPA and state access to the testing site to determine whether the testing complies with the terms and conditions of the permit.

References Cited in Chapter 12

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

Code of Federal Regulation, Title 40

AR0000575

- Part 152 - Pesticide registration and classification procedures
- Part 158 - Data requirements for registration
- Part 161 – Data requirements for antimicrobial pesticides
- Part 172 - Experimental use permits
- Part 180 - Tolerances and exemptions from tolerances for pesticide chemicals in food

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 3 - Registration of pesticides
- Section 5 - Experimental use permits
- Section 33 - Pesticide registration service fees

Federal Food, Drug and Cosmetic Act <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>

- Section 408 - Tolerances and exemptions for pesticide chemical residues

PR Notice 2011-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions> - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 13 - Devices

In this chapter:

- Devices - Introduction
- How to Obtain a Device Determination from EPA
- Devices Subject to Regulation
- Devices Not Subject to Regulation
- Requirements for a Device Subject to Regulation
  - Registration Not Required
  - Production Requirements
  - Labeling Requirements
  - Device Efficacy
  - Child-Resistant Packaging
- Import and Export of Devices
- Contacts for Additional Information
- References Cited in Chapter 13

Devices - Introduction

This chapter describes how EPA regulates pesticidal devices and clarifies which types of devices are subject to regulatory oversight and what requirements apply to them.

In 1976, EPA issued a Federal Register Notice concerning the regulatory status of devices <https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice>. In that notice, EPA also explained its interpretation of the distinction between a “pesticide” and a “device.” More information can be found on the EPA’s Pest Control Devices and Device Producers: 1976 Federal Register Notice webpage <https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice>.

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

FIFRA defines a device as any instrument or contrivance (other than a firearm) that is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom. Refer to FIFRA section 2(h) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>.

In general, if an article is an instrument or contrivance that uses physical or mechanical means to trap, destroy, repel, or mitigate any plant or animal life declared to be a pest at 40 CFR 152.5, it is considered to be a device and subject to regulation under FIFRA. However, devices are not subject to the registration requirements that apply to pesticides and pesticide products under FIFRA section 3. Further information can be found on EPA's Pest Control Devices Webpage. <https://epa.gov/pesticides/pesticide-devices-guide-consumers>

If a product consists of an object or article that incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA section 3. Also, if such a product is sold with any substance that functions as a precursor for creation of a pesticidal substance, the entire product is generally considered to be a pesticide and subject to registration under FIFRA section 3.

If the product is an instrument or contrivance and claims to control pests through physical or mechanical means, the product is considered to be a device, unless it is a firearm.

Distinctions among devices, pesticides, and pesticide application equipment can be illustrated by comparing products that are outwardly similar but are treated differently under FIFRA. For example, a bait station that is sold by itself to be used in conjunction with other products in the control of insects or rodents is considered to be pesticide application equipment and is not directly regulated under FIFRA, although the labels for registered pesticide products may require them to be used in bait stations in some or all applications.

If the same design of bait station is sold with toxic bait in it (or packaged with it for use in it), the entire product is considered a "pesticide product" and is regulated and labeled as such. If the bait station is sold with a sticky trap inside it (or is packaged with sticky traps that are to be placed inside it), the entire product is a device, and is regulated under FIFRA because it achieves pest control by physical means.

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. **Devices**
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>

18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>
19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>

- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- Pesticidal devices must be produced in an EPA registered pesticide-producing establishment. It is important to note that EPA establishment numbers, which are required for devices, are not the same as EPA pesticide registration numbers required for pesticide products. Obtaining an establishment number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or> is an administrative process, completed upon request to the EPA. In contrast, obtaining an EPA pesticide registration requires a fee for review of product specific data and is a longer process.
- EPA establishment numbers are composed of a company number, followed by a 2-letter U.S. State or 3-letter Country abbreviation, followed by the unique facility number (e.g., xxxx-PA-xx; xxxxx-CHN-xxxx)
- EPA Registration Numbers are composed of a company number followed by a product number (e.g., xxxxx-xxxx). For registered distributor products, the company number and product number are followed by the distributor company number (e.g., xxxxx-xx-xxxx)
- See Chapter 14 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or> for information on how to register a pesticide-producing establishment. Devices are also subject to certain labeling requirements. Refer to FIFRA section 2(q)(1) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> and 40 CFR Part 156.

How to Obtain a Device Determination from EPA

If you are uncertain about whether your product requires EPA registration as a pesticide, you may request a determination from EPA. If you would like a determination from EPA as to whether your product is considered a pesticidal device, please submit a request to the Agency using PRIA code M009. The cost is $2,482* and the timeframe is 4 months. Please submit the following information with your request:

- Submit 8570-1 application form (select "miscellaneous" and provide an explanation in the space provided);
- Submit a cover letter on company letterhead requesting a device determination and include as much of the following information as possible:
  - Your EPA issued company number;
  - The complete brand names of the product;
  - Complete copy of the label for the product, and a statement of all claims to be made for the product, including all written, printed, or broadcast claims made for the product;
  - Directions for use and warnings or cautionary statements;
  - All material distributed with the product;
  - A detailed written description of how the product works to kill, destroy, repel, or mitigate a pest;
  - Starting material inputs or ingredients or specifications used in the operation of the product. Ingredients in the product must be identified by common name and CAS number if applicable;
  - Schematic diagram or detailed engineering drawings, diagrams, flow diagrams or patent(s) application information. Note: if a patent(s) has been issued, please include copies;
  - Photographs of the product from all sides, including digital copies available upon request; and
  - Comparisons to current industry products;
- Provide proof of payment;

Once all of the submitted information is reviewed by the Agency, a determination letter will be issued to the applicant within the 4-month PRIA timeframe.

*There are provisions for waiving up to 75% of the fee if you qualify as a small business (waiver information is also on the website <https://epa.gov/pria-fees/pria-fee-waivers-small-businesses>). The fee waiver application must be submitted with the registration application.

- Fees may be reduced under some circumstances <https://epa.gov/pria-fees/overview-pria-fee-reduction-and-refund-formula>.

If you have questions, please contact us at OPP_FIFRA_Jurisdictional_Issues@epa.gov.

Devices Subject to Regulation

In a *Federal Register* notice published on November 19, 1976 (Pest Control Devices and Device Producers <https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice>), EPA stated that devices subject to FIFRA section 2(q)(1) and section 7 include, but are not limited to:

- certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances), and ultrasonic devices for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites;
- certain high frequency sound generators, carbide cannons, foils, and rotating devices for which claims are made to repel birds;
- black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper for which claims are made to kill or entrap certain insects; and
- mole thumpers, sound repellents, foils, and rotating devices for which claims are made to repel certain mammals.

Since that notice was issued, EPA has determined that products of the following types also fall within the definition of device:

- products that are claimed to control pests via **electromagnetic and/or electrical emissions** (e.g., hand held bug zappers, eletric flea combs);
- products that are claimed to control burrowing animals via **product-caused subterranean explosions**; and
- products that work via principles indicated in the 1976 *Federal Register Notice* for one category of pest but are claimed to control pests of different types (e.g., sticky traps for rodents (without attractants), light or laser repellents for birds, etc.).

Important Note: In applying the definition of "device" in FIFRA section 2(h), EPA examines each individual product on a case-by-case basis. For instance, the public should be aware that EPA has reviewed a number of individual products that claim to provide pest control through the use of electromagnetic radiation and has found these products to be devices within the meaning of section 2(h). In addition, EPA has found that a silver ion generating washing machine marketed with claims that odor causing bacteria will be killed on laundry must be registered as a pesticide. Read more about regulation of ion generating equipment <https://epa.gov/pesticide-registration/pesticide-registration-clarification-ion-generating-equipment>.

Devices Not Subject to Regulation

The November 19, 1976, *Federal Register* Notice Pest Control Devices and Device Producers <https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice> also provided examples of those types of devices that are not subject to regulation under FIFRA:

AR0000587

- devices that depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself; and
- devices that operate to entrap vertebrate animals.

Products generally falling within these two categories include rat and mousetraps, fly swatters, tillage equipment for weed control, and fish traps.

Requirements for a Device Subject to Regulation

Registration Not Required

A device is not required to be registered under FIFRA section 3. However, devices are subject to certain requirements of FIFRA as specified in 40 CFR 152.500.

Production Requirements

Pesticidal devices must be produced in a registered pesticide-producing establishment. Refer to 40 CFR 152.500(b)(2). See Chapter 14 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or> for information on registering a site.

Labeling Requirements

Devices are subject to the labeling requirements of FIFRA section 2(q)(1) and 40 CFR Part 156. These requirements are summarized below.

Misbranding - Under FIFRA section 2(q)(1) a device is considered to be misbranded and subject to enforcement action if:

- the labeling bears any statements, designs, or graphic representations that are false or misleading (see 40 CFR 156.10(a)(5));
- its packaging or wrapping does not conform to standards established pursuant to FIFRA section 25(c)(3) (as of 2010, such standards have yet to be established for devices);
- it is an imitation of, or is offered for sale under the name of another device;
- the label fails to bear the establishment number of the establishment where it was produced;
- any required information is not prominently displayed on the label;
- it lacks adequate directions for use; or
- it lacks an adequate warning or caution statement.

Device Efficacy

Unlike registrants of pesticide products, FIFRA does not require device producers to submit any data concerning either safety or efficacy of a device prior to distribution or sale. This is particularly important to note for antimicrobial pesticide devices that claim to disinfect, sanitize, and/or sterilize items or ambient air. Because microbial pests are not visible to the naked eye, users of such devices generally cannot evaluate the actual performance of the device. The device may be "misbranded" if labels, labeling, and/or websites for devices including general or specific efficacy claims include any statement, design, or graphic representation that is "false or misleading in any particular." Distribution or sale of a misbranded device is prohibited under FIFRA. Therefore, every producer or seller of devices is responsible for ensuring that these products perform as claimed, and that such performance claims are not misleading to the intended user.

Also, please note that some state laws have requirements for devices in addition to those imposed by FIFRA. Some state governments require registration of devices, including submission and review of efficacy data and labeling, before a device can be sold or distributed in that state. Therefore, compliance with FIFRA's requirements does not ensure that a device can be legally sold in those states. Click the link below for a contact list of state lead agencies.

http://npic.orst.edu/reg/state_agencies.html <http://npic.orst.edu/reg/state_agencies.html>

Child-Resistant Packaging

Devices are subject to child-resistant packaging (CRP) requirements when they meet certain toxicity and use criteria. For information concerning CRP requirements, see:

- Child-Resistant Packaging for Pesticides <https://epa.gov/pesticide-registration/child-resistant-packaging-pesticides>
- EPA regulations on child-resistant packaging --40 CFR 157.20 – 157.36

Child-resistant packaging is defined as packaging designed or constructed to be significantly difficult for children less than five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly. 40 CFR 157.21(b).

Import and Export of Devices

Please refer to FIFRA section 17 <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> for information concerning import and export requirements for devices. U.S. Customs regulations at 19 CFR 12.1(b) related to the implementation of FIFRA section 17 require, in part, that devices produced by foreign manufacturers and imported into the U.S. comply with all requirements applicable to domestic producers. In addition, the regulations require an importer to submit to EPA a Notice of Arrival of Pesticides and Devices <https://epa.gov/compliance/importing-and-exporting-pesticides-and-devices> (EPA Form 3540-1) for review and determination as to whether the shipment should be sampled and/or permitted entry into the U.S.

FIFRA section 17 states that no device produced solely for export to any foreign country shall be deemed in violation of FIFRA when prepared or packaged to the specifications or directions of the foreign producer, except that producers of such devices are subject to labeling requirements and certain misbranding restrictions found in sections 2(p) and 2(q) of FIFRA.

In addition, producers of devices are subject to record keeping and inspection requirements in accordance with section 8 of FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>.

Contacts for Additional Information

If you have any questions concerning regulatory requirements for devices that are not subject to registration, please contact:

OPP_FIFRA_Jurisdictional_Issues@epa.gov

References Cited in Chapter 13

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide registration and classification procedures
- Part 153 - Statement of policies and interpretations
- Part 156 - Labeling requirements for pesticides and devices
- Part 157 - Packaging requirements for pesticides and devices
- Part 167 - Registration of pesticide-producing establishments, submission of pesticide reports, and labeling
- Part 169 - Books and records of pesticide production and distribution

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 2 - Definitions
- Section 3 - Registration of pesticides
- Section 7 - Registration of establishments
- Section 8 - Books and records
- Section 9 - Inspection of establishments, etc.
- Section 12 - Unlawful acts
- Section 13 - Stop sale, use, removal, and seizure
- Section 14 - Penalties
- Section 17 - Imports and exports
- Section 25 - Child-resistant packaging

Federal Register Notice, Pest Control Devices and Device Producers <https://epa.gov/pesticide-registration/pest-control-devices-and-device-producers-1976-federal-register-notice>, (41 FR 51065), November 19, 1976

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON MARCH 1, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 14 – How to Obtain an EPA Company or Establishment Number or Change Address or Contact Information

In this chapter:

- What is an EPA company number
- How to obtain an EPA company number
- How to obtain an EPA establishment number
- Definition of an establishment
- Definition of produce
- Registering pesticide-producing and device-producing establishments
- Information requirements
- Reporting requirements
- How to report official company name, address or agent changes to EPA
- Contacts for additional information
- References cited in Chapter 14

What is an EPA Company Number

A “company number” is a unique identifier assigned to a company that wishes to register a pesticide (e.g., herbicide, rodenticide, or antimicrobial) with the U.S. Environmental Protection Agency (EPA). These companies are commonly called registrants.

A "company number" is also necessary for a company that plans to “produce” pesticides or devices. Such production requires the company to obtain a “Pesticide-Producing or Device-Producing Establishment

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Number." The company number is part of the establishment number.

How to Obtain an EPA Company Number

Registrants must obtain a company number prior to registering their first product with the Agency. For subsequent products or amendment to existing registrations, the registrant must refer to this company number. (Note: registrants who plan to produce their own products will also need to obtain an "establishment number <https://epa.gov/compliance/pesticide-establishment-registration-and-reporting>.")

The registrant must submit a signed letter on company letterhead to request a company number and establish an official address with EPA as described in the Agency's guidance "How to Obtain a Company Number and Register an Official Address <https://epa.gov/pesticide-registration/pesticide-registration-manual-how-obtain-company-number-and-register>." EPA will direct all future correspondence to the official address. The registrant must keep this official address record up to date.

In their request for a company number, foreign companies must designate a U.S. agent to receive correspondence and represent them in matters concerning their application. 40 CFR 152.50(b). U.S. registrants may also designate an agent. The letter should include a statement authorizing the agent to act in all matters concerning the registration of the product with EPA. It should also include a statement acknowledging that all official correspondence from EPA will be directed to the agent.

How to Obtain an EPA Establishment Number

When producing or formulating a pesticide, it is necessary to register the place(s) [or facility(ies)] where the pesticide or device is to be produced. This chapter describes how an applicant can obtain an establishment number for its facility.

FIFRA section 7 <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> governs pesticide establishments and recordkeeping. Detailed information concerning definitions, registration procedures, labeling, and reporting requirements is provided in 40 CFR Part 167, Registration of Pesticide and Active Ingredient Producing Establishments, Submission of Pesticide Report, and 40 CFR Part 169, Books and Records of Pesticide Production and Distribution.

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

Definition of an Establishment

The Code of Federal Regulations (40 CFR 167.3) defines an establishment as any site where a pesticide product, active ingredient, or device is produced, regardless of whether:

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. **How to Obtain an EPA Establishment Number**
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

AR0000598

- the site is independently owned or operated;
- site is domestic (i.e., located in the United States) and is producing the pesticide or device only for export; or
- the site is located in a foreign country and is producing the pesticide or device for importation into the United States.

Definition of Produce

The term "produce," as defined in 40 CFR 167.3, means "to manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced pursuant to [an Experimental Use Permit], any active ingredient or device, or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device."

Registering Pesticide-Producing and Device-Producing Establishments

To register an establishment, EPA Form 3540-8 <https://epa.gov/compliance/epa-form-3540-8-application-registration-pesticide-producing-and-device-producing>, Application for Registration of Pesticide-Producing Establishments must be completed and submitted to the Agency. The corresponding instructions provide information on how to properly complete the form and where to send it <https://epa.gov/compliance/epa-form-3540-8-application-registration-pesticide-producing-and-device-producing>.

Domestic Establishments - The completed application should be sent to the EPA Regional Office having jurisdiction over the state in which the company headquarters is located. EPA has 10 regional offices throughout the United States, which in turn oversee implementation and compliance with EPA programs and environmental standards in the 50 states and in the U.S. Territories. The instructions for Form 3540-8 list the Regional Offices' mailing addresses and telephone contacts.

Foreign Establishments - Foreign companies should submit their applications to EPA headquarters at the address listed in the instructions on how to properly complete Form 3540-8.

To request termination of a pesticide-producing or device-producing establishment, domestic establishments should notify the EPA Regional Office having jurisdiction over the state in which the company headquarters is located. Foreign establishments should notify the EPA Headquarters Office listed in the instructions for Registering Establishments <https://epa.gov/compliance/pesticide-establishment-registration-and-reporting-contacts> on the EPA Web page.

Read more about pesticide establishment registration <https://epa.gov/compliance/pesticide-establishment-registration-and-reporting>.

Information Requirements

Applications for the registration of an establishment require the following information:

AR0000599

- name and address of the company;
- EPA company number;
- type of ownership (individual, partnership, cooperative association, corporation, or any organized group of people whether incorporated or not);
- name(s) of new producing establishment(s);
- site address and the mailing address of the new producing establishments; and
- name of the company official or authorized agent, a signature, date of signature, and phone number.

Reporting Requirements

All active establishments are required to submit an annual production report on EPA Form 3540-16 <https://epa.gov/compliance/epa-form-3540-16-pesticide-report-pesticide-producing-and-device-producing>, Pesticide Report for Pesticide-Producing Establishments by March 1 of each year to the appropriate EPA Regional Office listed in the "Instructions for Completing EPA Form 3540-16 <https://epa.gov/compliance/epa-form-3540-16-pesticide-report-pesticide-producing-and-device-producing>". Refer to 40 CFR 167.85; 40 CFR 167.90. For new establishments, an initial report must be submitted no later than 30 days after the first registration of each establishment. Refer to 40 CFR 167.85(d). The records that must be maintained and the retention period are described in 40 CFR 169 .

Read more about pesticide establishment reporting <https://epa.gov/compliance/pesticide-establishment-registration-and-reporting>.

How to Report Official Company Name, Address or Agent Changes to EPA

Any changes to the official company name, address, withdrawal of an existing agent, appointment of a new agent or changes to any of the contact information listed under Information Requirements above should be reported to EPA as a separate transaction to ensure proper handling. Instructions for notifying the Agency of these changes are found in Agency's guidance "How to Report Official Company Name, Address or Agent Changes <https://epa.gov/pesticide-registration/pesticide-registration-manual-how-report-changes-company-name-or-address>". (Note: A sale, merger or spin-off of an EPA Company Number to another entity usually involves a Company Number Transfer [rather then just a Company Name Change]. See Chapter 16 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and> regarding transfers.

Report changes related to pesticide-producing establishments <https://compliancegov.zendesk.com/hc/en-us/articles/211428768-how-do-i-update-my-company-or-establishment-s-information->.

Contacts for Additional Information

For Company Numbers: How to request a company number <https://epa.gov/pesticide-registration/pesticide-registration-manual-how-obtain-company-number-and-register#howto>

For Official Address Changes: How to Report Official Company Name, Address or Agent Changes <https://epa.gov/pesticide-registration/pesticide-registration-manual-how-report-changes-company-name-or-address>

For Establishments: Information on registering an establishment and annual production reports may be obtained from the Pesticide Establishment Registration and Reporting Contacts <https://epa.gov/compliance/pesticide-establishment-registration-and-reporting-contacts>. EPA's Office of Enforcement and Compliance Assurance provides additional information on its Web page <https://epa.gov/compliance/pesticide-establishment-registration-and-reporting>.

References Cited in Chapter 14

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

Refer to Chapter 16 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and> for information on transfer of product registrations and data rights

Code of Federal Regulation, Title 40

- Part 167 - Registration of pesticide-producing establishments, submission of pesticide reports, and labeling
- Part 169 -Books and records of pesticide production and distribution

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act of August 3, 1996

- Section 7 - Registration of establishments

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.



An official website of the United States government

Pesticide Registration Manual: Chapter 15 – Submitting Data and Confidential Business Information

In this chapter:

- Submitting Data and Confidential Business Information
  - Overview
- Synopsis of FIFRA Section 10
  - Confidential Business Information
- Procedures for Submitting Data
- Data Formatting
  - Transmittal Document
  - Studies Must be Bound Separately
  - Supplements to Previously Submitted Studies
  - Replacement Pages for Previously Submitted Studies
  - Statement of Data Confidentiality Claims
  - Confidential Business Information Claims for Plant-Incorporated Protectant Submissions
  - Good Laboratory Practice Statement
  - Flagging Statement
  - Adverse Effects Submitted Under FIFRA 6(a)(2)
- Common Errors
- Contacts for Additional Information
- References Cited in Chapter 15

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Submitting Data and Confidential Business Information

This chapter includes information on how to submit data as well as special considerations concerning what data and information can be considered to be confidential business information.

Overview

Section 10 of FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> provides applicants with the ability to claim information as confidential, and requires EPA to protect information, which, in the Administrator's judgment, is entitled to confidential treatment.

Conversely, FIFRA section 10(d)(1) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> also provides that safety and efficacy information must be made available to the public. The exceptions to this mandatory disclosure requirement are listed in FIFRA section 10(d)(1)(A), (B), and (C) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>.

The procedures for asserting confidentiality claims for safety and efficacy information are described in 40 CFR 158.33, 40 CFR 161.33, and PR Notice 2011-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>.

Synopsis of FIFRA Section 10

Confidential Business Information

Section 10 of FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> specifies how and to what extent information submitted to the Agency under FIFRA may be afforded protection as confidential business information (CBI). FIFRA section 10(b) protects from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Certain annual facility data are also granted confidentiality under section 7(d) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>.

However, FIFRA section 10(d)(1) limits the types of data that may be claimed confidential. Safety and efficacy data (such as studies submitted to the Agency) on registered or previously registered pesticides are not

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

considered CBI and must be made available to the public. However, certain information is excluded from the definition of safety and efficacy data, and may therefore be claimed as CBI. These include the following:

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. **Submitting Data and Confidential Business Information**
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

AR0000608

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

AR0000609

- information that discloses manufacturing or quality control processes (FIFRA 10(d)(1)(A));
- information that discloses methods for testing and measuring the quantity of deliberately added inert ingredients (FIFRA 10(d)(1)(B)); and
- information that discloses the identity or percentage quantity of deliberately added inert ingredients (FIFRA 10(d)(1)(C)).

On rare occasions it may be necessary to reveal, under the authority of section 10(b), to federal agencies in public hearings or in findings of fact issued by EPA, formulas of products, even if confidential, to carry out other provisions of FIFRA, e.g., in cancellation or suspension hearings.

FIFRA section 10(e) permits EPA to give submitted confidential business information (CBI) to its contractors who are helping to do the work of the Agency. Such contractors are bound to protect this information to the same extent as EPA staff. The Agency will notify submitters of CBI whenever their data will be shared with a contractor. This is usually done by publishing a Notice in the *Federal Register* and always precedes giving the CBI to the contractor.

FIFRA section 10(g) prohibits the disclosure of certain information submitted by an applicant or registrant to any representative of a multinational pesticide producer or to anybody who intends to deliver such information to a multinational pesticide producer. Those persons may see certain abstracted data, or may view unabstracted data without copying.

FIFRA provides that, in certain circumstances, the EPA Administrator may disclose information that is otherwise protected. Such action is rare, and is described in FIFRA sections 10(b), 10(d)(3), 10(g), and 12(a)(2)(D).

The preceding section provides a brief overview of certain points regarding CBI. For more detailed information on policies related to EPA's handling of CBI, and allowances regarding CBI, refer to:

- FIFRA sections 7, 10, and 12 <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>
- 40 CFR Part 2

Procedures for Submitting Data

When data are submitted to the Agency, they are reviewed to determine whether they meet the data-formatting requirements in 40 CFR 158.32-33, 40 CFR 161.32-33, and PR Notice 2011-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>. The submitter will be notified of the results of this screening process.

Each study that meets the formatting requirements will be assigned a Master Record Identification Number (MRID) number and entered into OPP's data archive. These studies may then be retrieved at any time by referring to the MRID number. Refer to these MRID numbers instead of submitting additional copies of the studies to support additional applications for registration.

Please refer to 40 CFR 158.32-33, 40 CFR 161.32-33, and PR Notice 2011-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions> for a more detailed discussion on how to format data submissions.

Data submitted for certain actions may be submitted electronically as discussed in the guidance on electronic submissio <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>n. Applicants are advised to follow this guidance closely and contact EPA before developing their electronic submission.

- Contact OPP's Information Services Branch in the Information Technology & Resources Management Division <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-information-technology-and-resources> for assistance and additional information on data-formatting procedures.

Data Formatting

The following paragraphs summarize the major data-formatting requirements.

- Reminder: Each study should be submitted in triplicate. Data submitted for certain actions may be submitted electronically as discussed in the guidance on electronic submission <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>. Applicants are advised to follow this guidance closely and contact EPA before developing their electronic submission.
- Note: EPA Forms 8570-36 (Summary of Physical/Chemical Properties) <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms> and 8570-37 (Self-Certification Statement for Physical/Chemical Properties) <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms> should be placed in the study portion of an application package if they are applicable to that action. Information on self certification of product chemistry data is available in PR Notice 98-1 <https://epa.gov/pesticide-registration/prn-98-1-self-certification-product-chemistry-data-attachments>.

Transmittal Document

Each submission of data to the Agency must include a transmittal document. At a minimum, the transmittal document should include the name of the data submitter (or submitters, if more than one), the regulatory action the data are submitted in support of, and a listing of the data. The transmittal document can be a stand-alone document or may be incorporated into the cover letter for the action, at the submitter's option but may not include any confidential business information. A representative example of a stand-alone transmittal document can be found in PR Notice 86-5 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>.

- Ensure that all studies physically included in the submission are itemized.

AR0000611

EPA will send submitters an annotated copy of the transmittal document, provided the studies are accepted, with the corresponding MRID numbers. Please refer to PR Notice 2011-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions> for a sample transmittal document.

Studies Must be Bound Separately

Each study should be separately bound on 8.5 x 11-inch paper, single-sided, with black and white printing. All bindings should be secure, but easily removable to permit imaging.

Supplements to Previously Submitted Studies

Whenever information is submitted to supplement a previously submitted study, whether in response to a request by EPA or on the data submitter's own initiative, it must be prepared in the format required by 40 CFR 158.32-33, 40 CFR 161.32-33, and by PR Notice 86-5 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>.

Replacement Pages for Previously Submitted Studies

EPA will not accept unbound, unformatted, individual replacement pages or inadvertently omitted pages sent in for inclusion in previously submitted studies. However, EPA will accept a complete replacement version of the study that meets all the requirements 40 CFR 158.32-33 and of 40 CFR 161.32-33, and by PR Notice 2011-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>.

> - When submitting a complete replacement study, the title page of the replacement study should clearly identify the previously submitted study it replaces and include that study's MRID number.

The transmittal for the replacement study should fully explain both the relationship of the newly submitted study to the original study and the specific differences between the two versions. This will allow EPA reviewers to quickly discern whether or not the replacement study will significantly affect a review already under way or completed.

Statement of Data Confidentiality Claims

Each study submitted must include a Confidentiality Statement. The exact text of one of the two alternative forms of the statement (either the "Statement of No Data Confidentiality Claims" or "Statement of Data Confidentiality Claims") must appear on page 2 of the study (Refer to 40 CFR 158.33, 40 CFR 161.33, and PR Notice 2011-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions>.

When data are submitted, confidential data must be physically separated from the rest of the data (study) and placed in a confidential attachment at the back of the study report to enable the Agency to quickly identify the confidential data and to cross-reference it with the citations in the report.

Confidential Business Information Claims for Plant-Incorporated Protectant Submissions

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as Confidential Business Information (CBI), a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-incorporated protectant (40 CFR 174.9). To assert such a claim, the submitter must comply with all of the following procedures:

- Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.
- Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the points listed in 40 CFR 2.204(e)(4) in the substantiation. EPA will consider incomplete all plant-incorporated protectant submissions containing information claimed as CBI that are not accompanied by substantiation, and will suspend any applicable review of such submissions until the required substantiation is provided.

Good Laboratory Practice Statement

A statement of compliance or non-compliance with the Good Laboratory Practice Standards contained in 40 CFR Part 160 is required for all studies as defined in 40 CFR 160.3 that support or are intended to support pesticide applications.

- This statement should appear on page 3 of each study, and must be signed and dated by the study sponsor, the study submitter, and the study director.
- If the submitter neither conducted nor sponsored the study and therefore does not know whether or not the study complies with 40 CFR Part 160, then a statement to that effect, signed and dated by the submitter, is acceptable.

Flagging Statement

Flagging statements are required for certain types of subchronic and chronic toxicology data to alert EPA to potential adverse effects. Based on the results of the data, submitters must include one of two statements that indicate that the study either does or does not meet or exceed the triggers listed in 40 CFR 158.34 or 40 CFR 161.34.

- This statement, when required, should appear on page 4 of the study, and must be signed and dated by an authorized representative of the submitting company.

Adverse Effects Submitted Under FIFRA 6(a)(2)

Whenever an applicant becomes aware of any potential unreasonable adverse effects data meeting the statutory requirements of FIFRA section 6(a)(2), such data must be submitted to the Agency. The exact procedures concerning when data must be submitted are outlined in the following pesticide registration notices:

- 98-3 <https://epa.gov/pesticide-registration/prn-98-3-guidance-final-fifra-6a2-regulations-pesticide-product-registrants>,
- 98-4 <https://epa.gov/pesticide-registration/prn-98-4-additional-guidance-final-fifra-section-6a2-regulations-pesticide>, and
- 2000-8 <https://epa.gov/pesticide-registration/prn-2000-8-reportability-attorneys-opinions-and-conclusions-under-40-cfr>, as well as 40 CFR Part 159, Subpart D.

These studies are subject to the same data-formatting requirements as all other data submissions. They must be sent in triplicate to the Document Processing Desk, using distribution code 6(a)(2). FIFRA 6(a)(2) incidents are submitted in single copy. More information is found on the Web page: Incident Reporting by Pesticide Manufacturers <https://epa.gov/pesticide-incidents/incident-reporting-pesticide-manufacturers-registrants>.

Common Errors

In an analysis conducted by the Office of Pesticide Programs in 2006, EPA identified common formatting errors of submitted data. These common errors included:

- incorrectly formatted Confidential Business Information Statement,
- missing or incomplete Good Laboratory Practice (GLP) Standards Compliance Statement,
- incorrect pagination,
- legibility problems, and
- unsigned documents.

Important Notes: Following the instructions in PR Notice 86-5 is critical. Taking time to ensure that data submissions are in accordance with these formatting requirements will help avoid delays due to incorrectly formatted submissions and avoid rejection under FIFRA section 33(f)(4)(B) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> (see Chapter 5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>).

Contacts for Additional Information

If you have any questions concerning confidential business information as it may concern your application or how to format and submit supporting data, please contact the Information Technology & Resources Management Division, Information Services Branch <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-information-technology-and-resources>. Refer to Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> of this manual for contact names, telephone numbers, and addresses.

References Cited in Chapter 15

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the sources of these documents.

Code of Federal Regulation, Title 40

- Part 2 – Public Information
- Part 158 - Data Requirements for Registration
- Part 159 – Statements of Policies and Interpretations
- Part 160 – Good Laboratory Practice Standards
- Part 161 – Data Requirements for Registration of Antimicrobial Pesticides
- Part 174 – Procedures and Requirements for Plant-Incorporated Protectants

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act <https://epa.gov/node/111505> of August 3, 1996

- Section 7(d)
- Section 10
- Section 12

PR Notices <https://epa.gov/pesticide-registration/pesticide-registration-notices-year>

- PR Notice 2011-3 <https://epa.gov/pesticide-registration/prn-2011-3-standard-format-data-submitted-under-fifra-and-certain-provisions> - Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)
- PR Notice 98-1 <https://epa.gov/pesticide-registration/prn-98-1-self-certification-product-chemistry-data-attachments> - Self-Certification of Product Chemistry Data with Attachments
- PR Notice 98-3 <https://epa.gov/pesticide-registration/prn-98-3-guidance-final-fifra-6a2-regulations-pesticide-product-registrants> - Guidance on Final FIFRA 6(a)(2) Regulations for Pesticide Product Registrants
- PR Notice 98-4 <https://epa.gov/pesticide-registration/prn-98-4-additional-guidance-final-fifra-section-6a2-regulations-pesticide> - Additional Guidance on Final FIFRA Section 6(a)(2) Regulations for Pesticide Product Registrants w/Attachment
- PR Notice 2000-8 <https://epa.gov/pesticide-registration/prn-2000-8-reportability-attorneys-opinions-and-conclusions-under-40-cfr> - Reportability of Attorneys' Opinions and Conclusions Under 40 CFR Part 159 and FIFRA section 6(a)(2)

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 16 – Transfer of Product Registrations and Data Rights

In this chapter:

- Introduction
- Transfer of Product Registrations
  - Requirements for Approval of Registration Transfers
  - Transferor Submission of a Notarized Affirmation Statement
  - Timeframe for the Submittal of Data or Other Information
  - Requests for Time Extensions
  - Canceled Products and Unpaid Fees
- Transfer of Data and Data Rights
- Required Documentation for Processing Transfer of Data Rights
- Notarized Transferor Affirmation Statement for Transferring Data Rights
- Transfer of Company Ownership
- Contacts for More Information
- Transfer Deficiencies
- Sample Transfer Documents
- References Cited in Chapter 16

Introduction

This chapter discusses specific information to be submitted to EPA for the transfer of product registration and/or data rights from one person or company to another, as outlined in 40 CFR 152.135 (registration transfers) and 40 CFR 152.98 (data rights transfers).

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Applications for new products that are still pending registration (not registered) may also be transferred, as well as Special Local Need registrations (SLNs), Experimental Use Permits (EUPs), and Tolerance Petitions.

Transfer of Product Registrations

Upon receipt and approval by EPA of the documents described in 40 CFR 152.135(b), the registration is transferred to the new registrant. At that point, the new registrant is responsible for all actions concerning that registration and is liable as the registrant under FIFRA and the regulations. The new registrant is then permitted to distribute and sell the registered pesticide without having to apply for a new registration.

Requirements for Approval of Registration Transfers

Persons seeking approval of the transfer of a product registration are required to submit a document (a Transfer Agreement) signed by the authorized representative of the registrant of the product to be transferred (the transferor) and by the person to whom the product registration is to be transferred (the transferee), containing the following information (See 40 CFR 152.135(b)):

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. **Transfer of Product Registrations and Data Rights**
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>

18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>
19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>

- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- the name, address, phone number, EPA-assigned company number <https://epa.gov/pesticide-registration/pesticide-registration-manual-how-obtain-company-number-and-register>(4 pp, 118 K, PDF), and state of incorporation (if any) of the transferor;
- the name, address, phone number, EPA-assigned company number, and state of incorporation of the transferee (Note: If the transferee does not have an EPA-assigned company number, one should be requested before a transfer request is submitted);
- the product name(s) and EPA registration number(s), or the EPA File Symbol for pending products, of the products to be transferred;
- a statement that the transferor transfers irrevocably to the transferee all right, title, and interest in the EPA registration(s) listed by product name and EPA Registration Number in the document;
- a statement that the transferred registration(s) will not serve as collateral or otherwise secure any loan or other payment arrangement or executory promise, and that the registration(s) will not revert to the transferor unless a new transfer agreement is submitted to and approved by the Agency;
- a description of the general nature of the underlying transaction, e.g., sale, merger, spin-off, or bankruptcy transfer (no financial information need be disclosed);
- a statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and
- an acknowledgment by the transferee that his rights and duties concerning the registration under FIFRA and its implementing regulations will be deemed by EPA to be the same as those of the transferor at the time the transfer is approved.

Transferor Submission of a Notarized Affirmation Statement

In addition to the Transfer Agreement, the transferor must submit to the Agency, as required by 40 CFR 152.135(c), a notarized statement affirming that:

AR0000624

- the person signing the transfer agreement is authorized by the registrant to bind the transferor;
- no court order prohibits the transfer, and that any required court approvals have been obtained; and
- the transfer is authorized under all relevant federal, state and local laws and all relevant corporate charters, bylaws, partnerships, or other agreement.

Important Note: For the protection of all parties, it is highly recommended that the notarized Affirmation Statement be signed by an authorized person or company official other than the one signing the transfer agreement.

If the required documents are submitted, and no information available to the Agency indicates that the information is incorrect, the Agency will approve the transfer without requiring that the transferee obtain a new registration(s) and notify the transferor and the transferee of its approval.

The transfer will be effective on the date of Agency approval. Thereafter, the transferee will be regarded as the registrant for all purposes under FIFRA. The Agency cannot “postdate” or “backdate” a transfer, therefore the time it takes the Agency to process the transfer needs to be considered.

Important Note: When product registrations are transferred from one registrant to another, all restrictions, data requirements, conditions of registration, including timeframes for the submittal of data or other information, suspensions or any other requirements existing on the registration are transferred with the registration. The new registrant (transferee) is responsible for adhering to or complying with all such restrictions, data requirements, conditions of registration, timeframes, suspensions, or any other requirements that have been imposed on the acquired product registration.

Rights to exclusive use of data or compensation under FIFRA section 3(c)(1)(D) are separate from the registration itself and may be retained by the transferor, or may be transferred independently in accordance with the provisions of 40 CFR 152.98. If the registrant as the original data submitter wishes to transfer data rights at the same time as the registration is transferred, a single transfer document containing the information required by this section for both the registration and the data may be submitted.

Timeframe for the Submittal of Data or Other Information

The new registrant is responsible for the submittal of all required data according to the schedules already established by the Agency as a result of a Data Call-In under FIFRA section 3(c)(2)(B), or a condition of the registration under FIFRA section 3(c)(7), for the acquired product registrations. Failure to comply with these timeframes may result in the issuance of a Notice of Intent to Suspend the registration of the affected product under FIFRA section 3(c)(2)(B), or a Notice of Intent to Cancel the registration of the affected product under FIFRA section 6(e) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>.

Requests for Time Extensions

Requests for the extension of time to submit required data or other information from the new registrant, merely because it acquired the registration after the FIFRA section 3(c)(2)(B) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> data call-in was issued, or after the conditions of registration under FIFRA section 3(c)(7) were imposed, will not be granted. If new registrants have other valid reasons for delays in the testing that were clearly

outside of their control, then such a request for time extensions will be considered based on established procedures. If a registrant expects delays, and believes a time extension is necessary, the Agency should be informed as soon as possible and well before the due date.

Transfers that occur while a FIFRA section 3(c)(2)(B) data call-in is being issued or during the 90-day response time to the data call-in are subject to the same conditions expressed above.

Canceled Products and Unpaid Fees

The owner of a registration is responsible for payment of any new or previously unpaid fees for product maintenance and regulatory actions, including new applications, reregistrations, amendments, or tolerances.

Important Note: Neither registrations nor data can be transferred while fees, including maintenance fees, are listed as unpaid. Also, canceled or withdrawn products cannot be transferred.

Transfer of Data and Data Rights

The transfer of data and data rights is described in 40 CFR 152.98.

Transfer of data protection rights (including rights to exclusive use of data and/or data compensation) under FIFRA section 3(c)(1)(F) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>) is separate from the product registration itself and does not automatically transfer to the new registrant. These data and the respective ownership rights may be retained by the transferor or may be transferred independently in accordance with 40 CFR 152.98. If a registrant, as the original data submitter, wishes to transfer data rights at the same time as it transfers the registration, it may submit a single transfer document containing the information required by both 40 CFR 152.98 and 40 CFR 152.135.

Required Documentation for Processing Transfer of Data Rights

A person who possesses rights to exclusive use or compensation under FIFRA 3(c)(1)(F) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> may transfer such rights to another person by submitting a transfer document to EPA that contains the following information (See 40 CFR 152.98(a))

- The name, address, and state of incorporation (if any) of the original data submitter (the transferor).
- The name, address, and state of incorporation (if any) of the person to whom the data rights are being transferred (the transferee). (Note: Inclusion of phone number and e-mail address of both the transferor and transferee is highly recommended).
- Identification of each item of data being transferred including:
  - the name of the study or item of data;
  - whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires;
  - the name of the party or laboratory that conducted the study;
  - the date the study was submitted to the Agency;
  - the EPA document number assigned to the item of data (the Master Record Identification Number [MRID] or Accession Number), if known, if not known, the EPA administrative number (such as the EPA Registration Number, petition number, file symbol, or permit number) with which the item of data was submitted, such that the Agency can identify the item of data;
  - a statement that the transferor transfers irrevocably to the transferee all rights, titles and interest in the items of data named;
  - a statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and
  - the names, signatures, and titles of the transferor and transferee, **and the date signed**.

Note Regarding Exclusive Use: Exclusive use of data does not generally extend beyond 10 years from the date of registration of the pesticide. For more information see FIFRA section 3(c)(1)(F) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> and Chapter 10 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>.

Note: A transfer of data will not automatically be reflected on the Data Submitters List. If you wish for additions or changes to the Data Submitters List, please submit a separate request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Notarized Transferor Affirmation Statement for Transferring Data Rights

In addition to the Transfer Agreement, the transferor must submit to the Agency, as required by 40 CFR 152.98(b), a notarized statement affirming that:

> - the person signing this transfer agreement is authorized by the original data submitter to bind the data submitter;
> - no court order prohibits the transfer and any required court approvals have been obtained; and
> - this transfer is authorized under federal, state and local laws and relevant corporate charters, bylaws or partnership agreements.

Important Note: There are subtle differences in the language of the Affirmation Statement requirements outlined in 40 CFR 152.135 and 40 CFR 152.98. For transfers that include both registrations and data, one notarized Affirmation Statement may be submitted as long as it contains all of the information required by both subsections.

The Agency will acknowledge the transfer of the data by notifying both transferor and transferee, and will state the effective date of the transfer. Thereafter, the transferee will be considered to be the original data submitter of the items of data transferred for all purposes under FIFRA section 3(c)(1)(F) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> unless a new transfer agreement is submitted to the Agency

Important Note: It is the transferee's responsibility to ensure that copies of all data, and any underlying raw data, are received from the transferor. The Agency does not provide such copies of data to the new registrant. The Agency requires registrants to maintain copies of all studies and the relevant raw data for the life of the registration (see 40 CFR Part 169).

Important Note: Registration and/or Data transfers can only be executed between existing EPA company numbers (i.e. from EPA one company number to another EPA company number). If the transferee does not have an EPA-issued company number then, one must be requested before the transfer process can begin. To request for an EPA company number please see: Pesticide Registration Manual: How to Obtain a Company Number and Register an Official Address <https://epa.gov/pesticide-registration/pesticide-registration-manual-how-obtain-company-number-and-register#howto>. Note: if a company number is being transferred then, a new company number is not needed (see section "Transfer of Company Ownership").

Transfer of Company Ownership

The transfer of a company ownership, including all registrations and data must also follow the requirements for transferring registrations outlined in both 40 CFR 152.135 and 40 CFR 152.98. In the section of the Transfer Agreement that refers to registrations substitute "Company Ownership."

Company Number (Ownership) Transfers: If the transferring parties wish to transfer an existing EPA company number (Company Transfer) the following must be true:

- The transferor is (or will be effective on the date of transfer) no longer engaged in production, sale, or distribution of pesticides and is transferring all pesticide products and data to the transferee;
- The transferee will, in effect, assume the transferor's EPA company number; or
- The transferred EPA company number will become a separate division or D/B/A of the transferee's existing EPA company number.

Example: Joe's Pesticide Company (EPA company # 1234) decides to get out of the agricultural pesticide business and sell all of its agricultural pesticide registrations and data to Lou's Pesticide Company (EPA company # 5678). Since Lou's Pesticide Company already has EPA company # 5678, the parties may transfer EPA company number 1234 to Lou's Pesticide Company/Agricultural Division. From that point, EPA company number 1234* will be known by the name Lou's Pesticide Company/Agricultural Division (EPA company # 1234).

Another Example: The new company number could also be named Lou's Pesticide Company, D/B/A/ Joe's Agricultural Pesticides. These are just two examples.

Important Note: The owner of a company number must keep the Agency informed of its current name, address, and contact or authorized agent (40 CFR 152.122) as described in the Agency's guidance on company numbers <https://epa.gov/pesticide-registration/pesticide-registration-manual-how-report-changes-company-name-or-address>.

Submitting Transfer Requests and Contacts for More Information

To submit your transfer request or if you require additional information concerning the transfer of product registrations or data rights, please send all requests and inquiries to companyownershipchanges@epa.gov. ATTN: Louis Vaughn

---

Transfer Deficiencies

If a transfer submission is found deficient, a Notice of *Transfer Deficiency* will be issued by EPA, requesting additional information or corrections. It is the Agency's policy that if the requested information is not received within 60 days of the date of the Notice of *Transfer Deficiency*, the transfer will be considered to be inactive and abandoned by the transferor and no further action will be taken on the request.

Sample Transfer Documents

There is no required form for the Transfer Agreement or for the Transferor Affirmation Statement. However, as a convenience, a sample file is available: Registration and Data Transfer Agreement (rtf) <https://epa.gov/sites/default/files/2020-07/registration_and_data_transfer_sample_agreement-2020.rtf> (294.01 KB, July 16, 2020) . Company Transfer Agreement (rtf) <https://epa.gov/sites/default/files/2020-07/company_transfer_agreement_sample-2020.rtf> (151.06 KB, July 16, 2020)

AR0000629

References Cited in Chapter 16

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>for information on the source of these documents.

Code of Federal Regulation, Title 40

- Part 152 - Pesticide registration and classification procedures

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act <https://epa.gov/node/111505/> of August 3, 1996

- Section 3 - Registration of pesticides
- Section 6 - Administrative review; suspension

Pesticide Registration Home <https://epa.gov/pesticide-registration>
About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>
Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>
Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>
Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>
Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>
— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>
— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>
— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>
— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>
Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>
— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>
— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 17 – State Regulatory Authority

In this chapter:

- State Regulatory Authority
- State Issuance of Experimental Use Permit (EUP)
- State Registration of Special Local Needs
  - 24(c) Registration Regulations
  - Conditions for a Section 24(c) Registration
  - EPA's Responsibilities with the Section 24(c) Registration Program
- Emergency Exemptions under FIFRA Section 18
  - Types of Emergency Exemptions that May Be Authorized
  - Tolerances for Pesticide Chemical Residues in Food or Feed Owing to an Emergency Exemption
- References Cited in Chapter 17

State Regulatory Authority

FIFRA authorizes states to issue Experimental Use Permits (EUPs) <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>, Special Local Needs (SLNs) <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency> registrations, and to apply for Emergency Exemptions under specific conditions. This chapter provides detailed information relevant to state actions under FIFRA. State contact information can be found at the

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

AR0000636

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. **State Regulatory Authority**
18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- Association of American Pesticide Control Officials <https://aapco.org/>,
- National Association of State Departments of Agriculture <https://www.nasda.org/>, and
- EPA Regional Office contact information <https://epa.gov/aboutepa/#regional>.

In general, authorized states can issue experimental use permits only for the purpose of gathering data necessary to support the state registration of a pesticide to meet special local needs under FIFRA section 24(c) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> and for the purpose of experimentation.

Important Note: Most states require state registration in addition to federal registration. This chapter covers state actions under the federal registration regulatory framework but does not cover state registrations. Registrants should contact the appropriate state for information on obtaining a state registration.

State Issuance of Experimental Use Permit (EUP)

FIFRA section 5 <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> authorizes any state to issue an Experimental Use Permit in accordance with an EPA-approved state plan (40 CFR Part 172 provides detailed information on state experimental use permits).

Contact for More Information: For additional information concerning state EUPs, you should contact the pesticide regulatory authority in the state in which you wish to obtain a state EUP.

State Registration of Special Local Needs

FIFRA section 24(c) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> authorizes state lead agencies to register additional uses of federally registered pesticides (also called Special Local Needs (SLN) registrations or SLNs). The SLN permits distribution and use only in the registering state. The SLN is otherwise deemed a federal registration for all other purposes under FIFRA. All SLNs must be submitted to EPA for review subsequent to registration by the state.

See:

- 40 CFR Part 162, Regulations Pertaining to State Registration of Pesticides to Meet Special Local Needs <https://www.govinfo.gov/content/pkg/cfr-2014-title40-vol24/xml/cfr-2014-title40-vol24-part162.xml>; and
- Guidance on FIFRA 24(c) Registrations <https://epa.gov/pesticide-registration/guidance-fifra-24c-registrations>.

24(c) Registration Regulations

In general, section 24(c) registration regulations specify:

AR0000639

- types of registrations a state may grant under 40 CFR Part 162 <https://www.govinfo.gov/content/pkg/cfr-2014-title40-vol24/xml/cfr-2014-title40-vol24-part162.xml> (FIFRA section 24(c));
- circumstances under which a special local needs registration may be granted by a state; and
- circumstances under which the EPA Administrator may disapprove or invalidate a special local needs registration.

Important Notes:

- A state may not register an amendment to a federally registered manufacturing-use product (40 CFR 162.152(b)(1)(iv)).
- A state may only grant 24(c) registrations for voluntarily canceled uses of products after consulting with appropriate EPA personnel (40 CFR 162.152(b)(1)(iii)).
- A state may not register a new manufacturing-use product (40 CFR 162.152(b)(2)(iv)).

Conditions for a Section 24(c) Registration

Under FIFRA section 24(c) and its implementing regulations at 40 CFR Part 162, states are authorized to register new end use products or additional uses of federally registered pesticides if the following conditions exist:

AR0000640

- There is a **special local need** for that product use.
- The use, if a food or feed use, is covered by an appropriate tolerance or has been exempted from the requirement of a tolerance.
- The registration for the same use has not previously been denied, disapproved, suspended, or canceled by EPA, or voluntarily canceled by the registrant subsequent to EPA's issuance of a notice of intent to cancel because of health or environmental concerns about an ingredient contained in the product, unless EPA has reversed the original action.
- The registration is in accord with the purposes of FIFRA.
- If the proposed use or product falls into one of the following categories, the state must first determine that it will not cause unreasonable adverse effects on man or the environment:

    - its composition is not similar to any federally registered product;
    - its use pattern is not similar to any federally registered use of the same product or a product of similar composition; and
    - other uses of the same product, or uses of a product of similar composition, have had their registration denied, disapproved, suspended, or canceled by the Administrator.

Under the special local needs registration regulations, a state may register a new end-use product (not previously federally registered) meeting one of the following conditions (as well as the basic requirements for all special local needs registrations) (40 CFR 162.152(b)(2)(A) and (B)):

- a product that is identical in composition to a federally registered product but has differences in packaging, or in the identity of the formulator; or
- a product that contains the same active and inert ingredients as a federally registered product, but in different percentages.

In addition, 40 CFR 162.152(b)(2)(ii) sets forth the criteria for a state to register a new end-use product that contains a new combination of active, or active and inert, ingredients. A state may register such a product:

- only if each of the active ingredients in the new product is present because of the use of one or more federally registered products and if each of the inert ingredients in the new product is contained in a federally registered product

A state can issue a 24(c) registration for any use of a new end-use product containing an ingredient described in 40 CFR 162.152(a)(3) (i.e., registration for the same use has not previously been denied, disapproved, suspended, or canceled by the Agency, or voluntarily canceled subsequent to the issuance of a notice of intent to cancel that registration, unless the action is superseded by subsequent action of the Agency). A state may register any use of a federally registered product for which registration of other uses was denied, disapproved, suspended, or canceled if the new product is for a formulation or a use not included in the denial, disapproval, suspension, or cancellation, or if the federally registered use was voluntarily canceled without a prior notice of intent to cancel. However, a formulation or use not considered by the Agency during the aforementioned proceedings, or which was not the subject to a notice of intent to cancel, may be registered by a state only after the state consults with the appropriate Agency personnel regarding the application.

State Registration Procedures

Pesticide companies generally make requests for Special Local Need registrations to the specific state.

States require all applicants for registration to submit the following information:

- Name and address of the applicant and any other person whose name will appear on the labeling or in the directions for use.
- The name of the pesticide product, and if the application is for an amendment to a federally registered product, the EPA registration number of that product.
- A copy of proposed labeling, including all claims made for the product as well as directions for its use to meet the special local need, consisting of:
    - for a new product, a copy of the complete proposed labeling; or
    - for an additional use of a federally registered product, a copy of proposed supplemental labeling and a copy of the labeling for the federally registered product.
- The complete formula of the product, if the application is for a new product registration.
- Any other information that is required to be reviewed prior to registration under this section.
- Electronic reporting under state registration of pesticide products for special local needs. States that choose to receive electronic documents under the regulations pertaining to state registration of pesticides to meet special local needs must ensure that the requirements of 40 CFR Part 3 (Cross-Media Electronic Reporting) are satisfied by their state procedures for such registrations.

The state then reviews the application according to 40 CFR 162.153(b) – (g). Within 10 working days from the date the state issues, amends, or revokes a registration, the state notifies EPA, in writing, of the action.

EPA's Responsibilities with the Section 24(c) Registration Program

EPA's role is to ensure that each FIFRA section 24(c) registration meets the requirements of FIFRA, because these registrations become federal registrations unless the Agency disapproves them. EPA reviews the individual section 24(c) registrations and broadly oversees the states section 24(c) registration programs.

AR0000642

With section 24(c) registrations, states have the initial obligation to ensure that the SLNs they issue meet the requirements of FIFRA. Given the statutory time period for EPA review under section 24(c), EPA's review of SLN was not intended to be – and is not – the equivalent of its review of new registration actions under section 3. For example, EPA will generally not request data for amendments to federal products or new products that are substantially similar to currently registered products in composition and use.

For products registered under section 24(c) that are not substantially similar to a registered product, EPA generally will ask for only a brief summary of the data, the state's conclusions, and a certification that the product will not cause unreasonable adverse effects as defined in FIFRA for registration of pesticides (40 CFR 162.153). Refer to

- Guidance on FIFRA 24(c) Registrations, dated February 9, 1996 <https://epa.gov/pesticide-registration/guidance-fifra-24c-registrations>.

Quality Control and Conflict Resolution

EPA will also conduct general oversight by periodically reviewing all records of section 24(c) registrations to ensure that states and EPA have properly followed procedures and policies. If EPA finds problems, it will discuss and resolve them with the appropriate state(s).

EPA will make every effort to work out problems with states, but EPA retains the authority under 40 CFR 162.155 to suspend a state's authority to issue section 24(c) registrations, if necessary.

Grounds for Disapproving a State Registration

General Disapprovals

40 CFR 162.154(a) sets forth the process and requirements for disapproving a state registration that involves products with composition or use patterns that are not similar to a currently registered product. Reasons for disapproving these types of special local need registrations include, but are not limited to:

- probable creation of unreasonable adverse effects on man or the environment by the registered use;
- refusal of the registering state to submit information supporting the registration, i.e., application form (within 10 working days), labeling for the section 24(c) registration, Confidential Statement of Formula (new product only), final printed label (within 60 days), state revocation notice with date of revocation and reason(s) for revocation, and scientific studies supporting a no unreasonable adverse effects finding by the state (within 15 working days);
- failure of the information submitted by the state to support the decision to issue the section 24(c) registration under the standards set forth in 40 CFR 162.153.

Special Disapprovals

Under 40 CFR 162.154(b), EPA may disapprove any special local needs registration at any time (even beyond the 90-day period) if it is determined that the registration:

> - would constitute an imminent hazard; or
> - may result in a residue on food or feed exceeding, or not covered by, a tolerance, exemption, or other clearance under the FFDCA.

Once the special local needs use is registered under FIFRA, it is subject to any additional data requirements that may be required by EPA either as the result of a Reregistration Eligibility Decision Document, registration review <https://epa.gov/node/35867>, or other FIFRA section 3(c)(2)(B) data call-in. FIFRA section 24(c)(1).

Contacts for More Information

Additional information concerning applications for a state special local need registration should be addressed to the state in which you wish to make an application for a SLN registration. A listing of the various state pesticide agencies can be found in Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> of this manual.

Emergency Exemptions under FIFRA Section 18

FIFRA section 18 authorizes the Administrator to exempt state and federal agencies from any provision of FIFRA when emergency conditions exist that require an exemption. 40 CFR Part 166 sets forth the four types of emergency exemptions that may be authorized:

> 1. specific,
> 2. quarantine,
> 3. public health, and
> 4. crisis.

Notably, the section 18 exemption process can be relied upon as a time-limited authorization from EPA to use a pesticide for a use that is not registered if a determination is made that emergency conditions exist and that use of the pesticide will not cause unreasonable harm to human health or the environment.

Regulations in 40 CFR Part 166 establish procedures by which the Administrator may exempt a federal or state agency from the registration requirements of FIFRA.

AR0000644

Types of Emergency Exemptions that May Be Authorized

Specific Exemption (40 CFR 166.2(a) and 40 CFR Part 166, Subpart B)

A specific exemption may be authorized in an emergency condition to avert a significant economic loss or a significant risk to endangered species, threatened species, beneficial organisms, or the environment. EPA shall allow the use of a pesticide under a specific exemption for as long a period as is reasonably expected to be necessary, up to one year.

Quarantine Exemption (40 CFR 166.2(b) and 40 CFR 166, Subpart B)

A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to or not previously known to be widely prevalent or distributed within and throughout the United States and its territories. EPA shall allow use of a pesticide under a quarantine exemption for as long a period as is deemed necessary but in no case for longer than three years.

Public Health Exemption (40 CFR 166.2(c) and 40 CFR Part 166, Subpart B)

A public health exemption may be authorized in an emergency condition to control a pest that will cause a significant risk to human health. EPA shall allow the use of a pesticide under a public health exemption for as long a period as is reasonably expected to be necessary but in no case for longer than one year.

Note: Specific, quarantine, and public health exemptions may be renewed. Interim reports containing the information specified in 40 CFR 166.32(b) to the extent available shall be filed annually.

Crisis Exemption (40 CFR 166.2(d) and 40 CFR Part 166, Subpart C)

A crisis exemption may be utilized in an emergency situation when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption. A state or federal agency may issue a crisis exemption. The state or federal agency must notify EPA in advance of issuing a crisis exemption. EPA will review the proposed use to determine whether the crisis authority should not be exercised or the crisis exemption should be revoked.

Important Note: The crisis exemption may not be used to authorize a pesticide use if any of the following have occurred:

- EPA has informed the head of the federal or state agency, the Governor, or his/her official designee, not to issue such an exemption;
- the pesticide use has been suspended under section 6(c) of FIFRA;
- the pesticide use has been canceled following a notice issued under section 6(b) of FIFRA;
- the pesticide contains a new chemical; or
- the application proposes the first food use of a pesticide.

Duration of a Crisis Exemption (40 CFR 166.45)

A crisis exemption may be authorized for:

- only as long as is necessary to control the pest or conditions causing the emergency; and
- no longer than 15 days, unless an application requesting a specific, quarantine, or public health exemption for this use has been submitted to the Agency.

Tolerances for Pesticide Chemical Residues in Food or Feed Owing to an Emergency Exemption

Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> requires the establishment of time-limited tolerances or exemptions from tolerance requirements for residues of those pesticides exempted from regulation under FIFRA section 18.

The tolerances or exemptions must be consistent with the FFDCA safety standard, namely that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

More information on safety findings and information required for tolerance setting can be found in Chapter 11 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>, Tolerance Petitions

---

References Cited in Chapter 17

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

Code of Federal Regulation, Title 40

- Part 162 - State registration of pesticide products
- Part 166 - Exemption of federal and state agencies for use of pesticides under emergency conditions
- Part 172 - Experimental use permits

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act <https://epa.gov/node/111505> of August 3, 1996

- Section 3 - Registration of pesticides
- Section 5 - Experimental use permits
- Section 6 - Administrative review, suspension
- Section 18 - Exemption of federal and state agencies
- Section 24 - Authority of States

AR0000646

Standard Operating Procedure 4001.7: 24(c) Review Process <https://epa.gov/pesticide-registration/guidance-fifra-24c-registrations>, Office of Pesticide Programs, EPA, February 9, 1996

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

MAIN MENU

Search EPA.gov

Pesticide Registration

CONTACT US <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration>

Pesticide Registration Manual: Chapter 18 – Other Federal or State Agency Requirements

In this chapter:

- Introduction
- State Regulation of Federally Registered Pesticides
- Toxic Substances Control Act (TSCA)
  - Premanufacturing Notices for New Chemicals
  - Inert Ingredients Must Be on TSCA Inventory
  - Nonindigenous and Genetically Engineered Microbial Products Including Killed Microbials
- Uses of Pesticides Regulated by the Food and Drug Administration (FDA)
  - Antimicrobial Pesticides Regulated by FDA and EPA
  - Antimicrobial Uses Regulated Solely by the FDA
  - Antimicrobial Uses Subject to Dual Jurisdiction
  - Antimicrobial Pesticides Used on Medical Devices
  - Human Drugs
  - Animal Drugs
- Use of Pesticides Regulated by the Federal Aviation Administration (FAA)
- Use of Pesticides Regulated by the Department of Transportation (DOT)
  - Shipping (Transportation) of Pesticides
- U.S. Department of Agriculture (USDA)
  - National Organics Program
- Occupational Safety and Health Administration (OSHA) Requirements
- References Cited in Chapter 18

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Introduction

Sometimes even after obtaining a federal registration, a pesticide registrant may need to meet other federal, state, or local requirements. The following listing is only intended to provide general information on some of these requirements and/or to provide a point of contact. It should be noted that the listing is not all inclusive. It remains the applicant's and the registrant's responsibility to comply with all federal, state, or local regulations.

State Regulation of Federally Registered Pesticides

FIFRA section 24(a) <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act> provides that "A state may regulate the sale or use of any federally registered pesticide or device in the state, but only if and to the extent that the regulation does not permit any sale or use prohibited by this Act."

Even though a federal registration may have been obtained for a given pesticide product allowing the distribution and sale of the product within the United States, a state may have additional requirements that must be met before the pesticide product can be distributed or sold within that state. The requirements vary from state to state, and may include:

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

AR0000652

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>
18. **Other Federal or State Agency Requirements**

19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

AR0000654

- additional data requirements,
- additional restrictions on pesticide use within its jurisdiction, and
- licensing requirements.

The applicant should contact each state in which the product is to be marketed to determine what additional requirements may affect the sale, distribution, or use of that product.

Guidance on FIFRA Section 24(c) registrations. <https://epa.gov/pesticide-registration/guidance-fifra-24c-registrations>

Toxic Substances Control Act (TSCA)

The Environmental Protection Agency's (EPA's) New Chemicals Program <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>, located in the Office of Pollution Prevention and Toxics, was established to help manage the potential risk from chemicals new to the marketplace. It is mandated by section 5 of the Toxic Substances Control Act (TSCA) <https://www.govinfo.gov/app/collection/uscode/>. TSCA, enacted by Congress in 1976, gives EPA broad authority to identify and control substances that may pose a threat to human health or the environment.

Premanufacturing Notices for New Chemicals

The New Chemicals Program functions as a "gatekeeper" that can identify conditions up to and including a ban on production to be placed on the use of a new chemical before it is entered into commerce. Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required by section 5 of TSCA to provide EPA with notice before initiating the activity. This premanufacturing notice, or PMN, must be submitted at least 90 days before the manufacture or import of the chemical.

Inert Ingredients Must Be on TSCA Inventory

All applicants for new inert ingredients need to confirm that their chemical is on the TSCA inventory (either “grandfathered in” or reviewed in the PMN program). If it is not, they need to go through the PMN process to get the inert on the inventory as an initial step toward its approval as an inert ingredient. Refer to the TSCA New Chemicals Program <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca> for further information.

Nonindigenous and Genetically Engineered Microbial Products Including Killed Microbials

Products of recombinant DNA technology are also regulated by EPA under TSCA by the Office of Pollution Prevention and Toxics (OPPT) during stages of production before the products become pesticides (such as during fermentation). A Premanufacturing Notice (PMN) may be required for these products. PMNs are not required while the product is under research and development (such as under an EUP), and are also not required for nonindigenous or trans conjugant organisms. For information on TSCA requirements related to microbial pesticide production contact:

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Chemical Control Division (7405)
New Chemicals Notice Management Branch
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Telephone: Toxics Assistance Information System (202) 554-1404
OPPT New Chemicals Web site <https://epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>

Uses of Pesticides Regulated by the Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) and EPA have several areas of mutual regulatory responsibility, which may require review by one or both agencies. The following is a brief summary of these areas and the Antimicrobial Web pages <https://epa.gov/pesticide-registration/antimicrobial-policy-and-guidance-documents> should be consulted periodically for any recent agreements between FDA and EPA on emerging technologies and issues.

Antimicrobial Pesticides Regulated by FDA and EPA

Antimicrobial agents are subject to regulation by FDA and EPA, either singly or jointly, depending upon the use. The most complex area involves the use of antimicrobials in or on food. The descriptions provided below address both food and nonfood uses regulated by FDA; antimicrobial food uses subject to dual jurisdiction, regulated by both FDA and EPA; and antimicrobial food uses regulated by EPA.

Antimicrobial Uses Regulated Solely by the FDA

The following are uses of antimicrobials that are regulated exclusively by FDA. No section 3 registration under FIFRA is required.

- Use of an antimicrobial in/on processed food.
- Application of an antimicrobial to process water in a food processing facility where the water is only a vehicle for transporting the antimicrobial chemical to the processed food.
- Use of an antimicrobial in/on living man or animal.
- Use of an antimicrobial in/on cosmetics.
- Use of an antimicrobial in/on beverages.
- Use of an antimicrobial in/on drugs.
- Use of an antimicrobial in/on animal feed.

Antimicrobial Uses Subject to Dual Jurisdiction

The following are antimicrobial food uses that are subject to dual jurisdiction. FDA regulates residues that may occur on processed food through the indirect food additives process, which is described in 21 CFR Parts 175 - 178. These uses are also considered pesticide uses subject to registration under FIFRA. However, a food additive clearance must be obtained from FDA before EPA will approve the application. Inquiries to FDA should be directed to the address listed at the end of this section.

- Treatment of raw agricultural commodities in a food processing facility.
- Application of an antimicrobial to process water in a food processing facility to control a pest in the water (e.g., pulp and paperboard use, use in cane-sugar and beet-sugar mills).
- Production of food packaging.
- Production of food contact articles other than food packaging; no intended effect on the surface of the article.

Antimicrobial Food Uses Regulated Solely by EPA

The following are antimicrobial food uses regulated exclusively by EPA:

- Use of an antimicrobial for pre- and/or post-harvest field use on crops.
- Use of antimicrobials by consumers on raw agricultural commodities (e.g., home gardens, home produce washes).
- Application of an antimicrobial to process water for post-harvest use (field washing) of raw agricultural commodities.
- Application of an antimicrobial to animal drinking water.
- Treatment of permanent or semi-permanent food contact surfaces (sanitizers).
- Use of an antimicrobial in the production of food contact articles, other than food packaging, where the antimicrobial is intended to have an ongoing effect on the article's food contact surface or in food that may contact the article.

Contact Information for FDA

Inquiries and questions concerning establishment of indirect food additive regulations and FDA jurisdiction should be sent to the following address:

Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
FDA Web site <http://www.fda.gov/aboutfda/centersoffices/officeoffoods/cfsan/default.htm>

Antimicrobial Pesticides Used on Medical Devices

An antimicrobial agent used on medical devices is considered by FDA to be an accessory to a medical device. Accordingly, FDA requires pre-market notification under section 510(k) of the FFDCA <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> for marketing of such agents. FDA reviews the safety and efficacy of these antimicrobial products. Approval by both FDA and EPA must be obtained before these products may be sold or distributed. Section 510(k) petitions may be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Division of Gastroenterology-Urology and General Use Devices
Office of Device Evaluation
(HFZ-332) 8757 Georgia Avenue
Silver Spring, MD 20910
CDRH Web site <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/default.htm>

Human Drugs

FDA and EPA have areas of mutual responsibility with respect to applications for drugs under FFDCA <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act> and for registration of pesticides under FIFRA <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>. In 1971, FDA and EPA issued a “Memorandum of Agreement” stating which agency has primary or secondary responsibility on specific matters (Federal Register Notice, 36 FR 24234). This agreement was updated in 1973 (38 FR 24233), in 1979 (44 FR 63749), in 1993 referring to pediculicides (58 FR 65452), and in 1994 (PR Notice 94-6 <https://epa.gov/pesticide-registration/prn-94-6-pesticide-products-registered-use-humans-control-lice-pediculicides>). Briefly, EPA has primary jurisdiction for disinfectants and sanitizers.

FDA has primary jurisdiction for new human drugs, and products that are intended to:

- control parasites on humans,
- relieve the effect of insect bites,
- prevent diaper rash through treatment of diapers,
- treat athletes foot, and
- treat drinking water to control animal parasites or diseases.

Questions on these areas of jurisdiction may be referred to EPA's Antimicrobials Division for disinfectant and sanitizer treatments, and Registration Division, Insecticide Branch, for human or animal drug/pesticide treatments. Please refer to Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> of this manual.

Animal Drugs

The EPA and FDA are currently in discussion to determine what categories of products are regulated as pesticides and what categories of products are regulated as animal drugs. Applicants should contact either FDA or EPA for additional information.

Use of Pesticides Regulated by the Federal Aviation Administration (FAA)

Antimicrobial Fuel Additives

Any pesticide product intended for use in aviation fuel must have the approval of the Federal Aviation Administration (FAA) for use in aircraft engines. Persons who wish to obtain FAA approval must submit their request to:

> U.S. Department of Transportation
> Federal Aviation Administration
> FAA Flight Standards Service
> Engineering and Manufacturing Division
> Washington, DC 20591
> Telephone number: (202) 366-4000
> FAA Flight Standards Service Web site <http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/afs/>

Use of Pesticides Regulated by the Department of Transportation (DOT)

Shipping (Transportation) of Pesticides

The U.S. Department of Transportation (DOT) and EPA have several areas of mutual regulatory responsibility, which may require review by one or both agencies.

The Hazardous Material Transportation Uniform Safety Act, as amended in 1990, requires that pesticides being shipped are properly packaged, marked, and labeled. If the pesticide to be shipped is considered a hazardous material, it will need to bear the proper DOT Hazard Warning Labels prominently on the product labeling. Also, depending upon the size of the shipment, trucks may need to be placarded.

If you wish to transport pesticides that may present physical or chemical hazards, you must obtain shipping papers from DOT before such shipment.

AR0000659

For additional information on the transportation of pesticides, and how to obtain shipping papers, contact:

> Department of Transportation
> Office of Hazardous Material Standards (Rm. 8100)
> 400 7th St., S.W.
> Washington, DC 20590-0001
> Phone: (202) 366-4488
> HAZMAT Web site <https://www.phmsa.dot.gov/about-phmsa/offices/office-hazardous-materials-safety>

U.S. Department of Agriculture (USDA)

Any organism (including plants) may be considered a potential plant pest. Such organisms may be regulated under either the Plant Pest Act and/or the Plant Quarantine Act. Such organisms may require a permit for import and/or introduction testing, and use. For information on USDA permit requirements contact:

> U.S. Department of Agriculture
> Plant Protection and Quarantine Service
> Unit 133
> 4700 River Road
> Riverdale, MD 20737
> Telephone: (301) 734-8896
> USDA Plant Web site <https://www.aphis.usda.gov/aphis/ourfocus/planthealth>

National Organics Program

The National Organic Program (NOP) <https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program> develops, implements, and administers national production, handling, and labeling standards for organic agricultural products. The NOP also accredits the certifying agents (foreign and domestic) who inspect organic production and handling operations to certify that they meet USDA standards. Pesticide Registration Notice 2003-1 <https://epa.gov/pesticide-registration/prn-2003-1-labeling-pesticide-products-under-national-organic-program> describes how registrants can obtain EPA approval of label language indicating that all ingredients (active and inert) in a pesticide product and all uses of that pesticide meet the criteria defined in the USDA NOP Rule.

Occupational Safety and Health Administration (OSHA) Requirements

As employers, pesticide manufacturers and registrants may be subject to requirements designed to promote worker safety and health under the laws administered by OSHA.

AR0000660

OSHA under 29 CFR 1910 has established health standards (such as permissible exposure limits for certain hazardous chemicals) and safety standards (such as providing personal protective equipment). These standards may be applicable to workplaces where pesticides are manufactured, handled or stored, if these hazards are present. In addition, generally the Hazard Communication Standard (HCS) (29 CFR 1910.1200 requires labeling, material safety data sheets, and training for workers who may be exposed to hazardous chemicals. One exception is that pesticides bearing an EPA-approved FIFRA label are not subject to the OSHA label requirements, though the HCS data sheet and training requirements may still apply.

More information on OSHA requirements is available on OSHA's web site <https://www.osha.gov/>.

References Cited in Chapter 18

Refer to Chapter 19 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications> for information on the source of these documents.

Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, as amended by the Food Quality Protection Act <https://epa.gov/node/111505> of August 3, 1996

- Section 3 - Registration of pesticides
- Section 24 - Authority of States

Toxic Substances Control Act <https://epa.gov/laws-regulations/summary-toxic-substances-control-act>

- Section 5 - New Chemicals Program

Federal Food, Drug and Cosmetic Act <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>

- Section 510(k)

Federal Register Notices

- 36 FR 24234
- 38 FR 24233
- 44 FR 63749
- 58 FR 65452

PR Notice 94-6 <https://epa.gov/pesticide-registration/prn-94-6-pesticide-products-registered-use-humans-control-lice-pediculicides> - Pesticide Products Registered for Use on Humans to Control Lice (Pediculicides)

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 19 - How to Obtain Publications

In this chapter:

- Documents Available from EPA
  - Pesticide Registration Notices
- *Federal Register* Notices
- Documents Available from the Government Printing Office
- Documents Available from NTIS

Documents Available from EPA

The Agency has made most of its recent publications and documents available on the Internet. Documents including the registration forms <https://epa.gov/pesticide-registration/completing-and-submitting-pesticide-registration-forms>, Reregistration Eligibility Documents, and laws such as Federal Insecticide, Fungicide, and Rodenticide Act <https://epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act>, and the Federal Food, Drug, and Cosmetic Act (FFDCA <https://epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act>), etc. are available on the EPA Web site.

Copies are available from the following address:

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>

18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>
19. **How to Obtain Publications**
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Registration Support Branch (7505P)
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Telephone: (703) 305-6549

Other publications from the Office of Pesticide Programs may be obtained from EPA's National Service Center for Environmental Publications by contacting 1-800-490-9198 or faxing 301-604-3408.

Pesticide Registration Notices

Pesticide Registration Notices (PR Notices) are mailed to registrants of record when issued. Recent and current PR Notices can also be accessed directly on the Pesticide Registration Notices <https://epa.gov/pesticide-registration/pesticide-registration-notices-year> website. Other or back copies are available from the National Technical Information Service as described below.

Federal Register Notices

The *Federal Register* is available for examination at government depository libraries and many other libraries. A complete listing of Government Depository Libraries is available without charge from The Library, U.S. Government Printing Office, 5236 Eisenhower Avenue, Alexandria, VA 22304.

- View the list of depository libraries <https://www.fdlp.gov/>.
- View all *Federal Register* documents published from 1994 forward <https://www.govinfo.gov/app/collection/fr/>.

Documents Available from the Government Printing Office

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 40, Protection of the Environment (40 CFR), comprises 32 volumes, and regulation of pesticides is specifically covered by:

- 40 CFR Part 2 - Public Information (contained in **Volume 1, 40 CFR Parts 1 to 49**); and
- 40 CFR Parts 150 to 189 - Chapter I, Subchapter E—Pesticide Programs (contained in **Volume 23, 40 CFR Parts 150 to 189**)

These documents are available for purchase from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington DC 20402. They can also be accessed directly on the GPO Web site.

The Code of Federal Regulations is also available for examination at government depository libraries and many other libraries.

View a listing of libraries where the Code of Federal Regulations is available <https://www.fdlp.gov/>.

A complete listing of Government Depository Libraries is available without charge from:

> The Library
> U.S. Government Printing Office
> 5236 Eisenhower Avenue
> Alexandria, VA 22304

Documents Available from NTIS

Documents can be purchased from National Technical Information Service (NTIS), using the NTIS search engine <https://www.ntis.gov/> to identify the document by title or topic if its NTIS product code is not known. The documents that can be ordered from NTIS include such items as:

- Pesticide Registration Notices (copies not available on the Web)
- Label Review Manual
- Reregistration Eligibility Documents
- Antimicrobial Pesticide Reregistration Eligibility Documents
- Pesticide Fact Sheets
- Special Review Documents
- OPPTS Harmonized Test Guidelines
- Standard Evaluation Procedures
- Pesticide Assessment Guidelines
- Registration Standards Report
- Publications prior to the EPA Web site

The address for the National Technical Information Service (NTIS) is:

National Technical Information Service <https://www.ntis.gov/>
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161
Telephone: 1-800-553-6847
(https://www.ntis.gov/)

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 20 – Forms and How to Obtain Them

In this chapter:

- Forms and how to obtain them
- EPA forms
- Pesticide forms overview table

Forms and How to Obtain Them

The forms required to be submitted when applying for the registration of a pesticide product, experimental use permit, or distributor registration are listed below. A table at the end of this chapter describes the circumstances under which each of the forms should be submitted. Copies of these forms also are available from:

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Notifications and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>

18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>
19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. **Forms and How to Obtain Them**
21. Directions for Submitting Applications and Contacting EPA <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications>

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

AR0000679

U.S. Environmental Protection Agency
Registration Support Branch, Registration Division (7505P)
Attn: Registration Forms
Office of Pesticide Programs
1200 Pennsylvania Avenue, N.W.
Washington DC 20460
or e-mail: Eleanor Thornton (thornton.eleanor@epa.gov)

For guidance in selecting the appropriate form contact one of OPP's product registration contacts <https://epa.gov/pesticide-contacts/contacting-epa-about-regulating-pesticides-issues>.

Information on completing and submitting registration forms <https://epa.gov/pesticide-registration/completing-and-submitting-pesticide-registration-forms>.

EPA Forms

These forms are in PDF format, which allows them to be completed (filled out) on-screen, printed, and submitted to EPA.

EPA Form No.	Title
8570-1 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Application for Pesticide Registration/Amendment (Note: Do not be concerned that the Internet copy of this form may not have a red number in the upper right-hand corner. EPA will fill in this number upon receipt.)
8570-4 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Confidential Statement of Formula
8570-5 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Notice of Supplemental Distribution of a Registered Pesticide Product
8570-17 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Application for an Experimental Use Permit
8570-25 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need
8570-27 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Formulator's Exemption Statement

EPA Form No.	Title
8570-28 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Certification of Compliance with Data Gap Procedures
8570-32 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data
8570-34 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Certification with Respect to Citations of Data (as referenced in PR Notice 98-5 <https://epa.gov/pesticide-registration/prn-98-5-new-forms-certification-respect-citation-data>)
8570-35 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Data Matrix (as referenced in PR Notice 98-5 <https://epa.gov/pesticide-registration/prn-98-5-new-forms-certification-respect-citation-data>)
8570-36 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Summary of the Physical/Chemical Properties (as referenced in PR Notice 98-1 <https://epa.gov/pesticide-registration/prn-98-1-self-certification-product-chemistry-data-attachments>)
8570-37 <https://epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>	Self-Certification Statement for the Physical/Chemical Properties (as referenced in PR Notice 98-1 <https://epa.gov/pesticide-registration/prn-98-1-self-certification-product-chemistry-data-attachments>)

The following forms may also be required in order to sell or distribute a pesticide product or device in the United States and can be obtained from the EPA Regional Office where your company headquarters is located or via links in the following list. Foreign establishments should contact the HQ EPA Office of Compliance. See Chapter 21 <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-21-directions-submitting-applications> for listing of all addresses.

EPA Form No.	Title
3540-1 <https://epa.gov/compliance/epa-form-3540-1-notice-arrival-pesticides-and-devices>	Notice of Arrival of Pesticides or Devices
3540-8 <https://epa.gov/compliance/epa-form-3540-8-application-registration-pesticide-producing-and-device-producing>	Application for Registration of Pesticide-Producing Establishments and Instructions for Application
3540-16 <https://epa.gov/compliance/epa-form-3540-16-pesticide-report-pesticide-producing-and-device-producing>	Pesticide Report for Pesticide-Producing and Device-Producing Establishments and Instructions for Report

Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>

The Table lists which forms are needed for a registration, a label amendment, a formulation amendment and an Experimental Use Permit.

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 26, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

An official website of the United States government

Pesticide Registration Manual: Chapter 21 – Directions for Submitting Applications and Contacting EPA

In this chapter:

- Directions for Submitting Applications and Contacting EPA
  - Where to Send Applications for Product Registrations
- Using the Correct Distribution Code
  - Distribution Codes for OPP Regulatory Divisions
- Where to Send Applications for Pesticide and Pesticide Device Producing Establishments
- Organizational Charts
- Contacting EPA

Directions for Submitting Applications and Contacting EPA

PLEASE NOTE: An alternative to hard copy deliveries is available for certain types of actions via the Pesticide Submission Portal. The Portal is accessed through EPA's Central Data Exchange (CDX) Network <https://cdx.epa.gov/> and requires user registration.

Registrants currently submitting CDs or DVDs using the e-Dossier downloadable tool or their own builder tools using EPA's XML guidance can use the portal and forego courier delivery costs. Additional information, including a user guide and updated XML guidance, is available on EPA's Electronic Submission for Pesticide Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications> page.

Registration Manual Table of Contents

Pesticides Registration Manual Home Page <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Introduction <https://epa.gov/pesticide-registration/pesticide-registration-manual-introduction>

How to Register a Pesticide Product – A Guide for Applicants New to the Process <https://epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>

1. Requirements for Pesticide Registration and Registrant Obligations <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide>

Where to Send Applications for Product Registrations

Applications for registration, petitions, experimental use permits, etc., must be sent to the following address, using the appropriate distribution code (see below):

2. Registering a Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product>
3. Additional Considerations for Biopesticide Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-3-additional-considerations>
4. Additional Considerations for Antimicrobial Products <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations>
5. Registration Fees <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-5-registration-fees>
6. Amending a Registered Pesticide Product <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide>
7. Establishment and Minor Formulation Amendments <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-7-notifications-and-minor-formulation>
8. Inert Ingredients <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients>
9. Supplemental Distribution of a Registered Pesticide <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-9-supplemental-distribution-registered>

AR0000687

10. Data Compensation Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-10-data-compensation-requirements>
11. Tolerance Petitions <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions>
12. Applying for an Experimental Use Permit <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit>
13. Devices <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
14. How to Obtain an EPA Establishment Number <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-14-how-obtain-epa-company-or>
15. Submitting Data and Confidential Business Information <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-15-submitting-data-and-confidential>
16. Transfer of Product Registrations and Data Rights <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-16-transfer-product-registrations-and>
17. State Regulatory Authority <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>

AR0000688

18. Other Federal or State Agency Requirements <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-18-other-federal-or-state-agency>
19. How to Obtain Publications <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-19-how-obtain-publications>
20. Forms and How to Obtain Them <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>
21. **Directions for Submitting Applications and Contacting EPA**

Appendices

- Appendix A: Guidance Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-guidance-documents>
- Appendix B: Examples of Registrant Documents <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-b-examples-registrant-documents>
- Appendix C: Pesticide Forms Overview Table <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-c-pesticide-forms-overview-table>
- Appendix D: Examples of Completed Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-appendix-d-examples-completed-forms-0>

- by **U.S. Postal Service Delivery**:

  U.S. Environmental Protection Agency
  Document Processing Desk (Distribution Code)
  Office of Pesticide Programs (7504P)
  1200 Pennsylvania Avenue, N.W.
  Washington DC 20460-0001

- or by **Personal (hand)/Courier Service Delivery**:

  U.S. Environmental Protection Agency
  Document Processing Desk (Distribution Code)
  Office of Pesticide Programs (7504P)
  1200 Pennsylvania Ave. NW
  Washington, D.C. 20460

The Document Processing Desk (DPD) is the point of delivery for all hard copy deliveries addressed to OPP's regulatory divisions. The DPD does not accept deliveries addressed to OPP's non-regulatory divisions. Hours of operation for the DPD are: 8:00 A.M. to 4:00 P.M. Monday through Friday, excluding Federal holidays.

View directions to One Potomac Yard and security/building access information <https://epa.gov/aboutepa/visiting-epa-headquarters#tab-2>.

Using the Correct Distribution Code

Using the correct *distribution code* enables the Agency to process applications more quickly, since the application can be quickly identified and routed. Please refer to the list below for a selection of codes to be used in making a submission to the Office of Pesticide Programs. Failure to use the appropriate code can lead to delays in processing your action.

Distribution Codes for OPP Regulatory Divisions

Section 3 - Product Registrations

Submission Type	Distribution Code
Application for New Product Registration	REGFEE
Non-Fast Track Amendment to Existing Registration	REGFEE
Fast Track Amendment to Existing Registration	AMEND
PRIA Fee Waiver Request	WAIVER
Request to Withdraw a Pending Registration Application	WD

Submission Type	Distribution Code
Certification of Registration (Gold Seal letter)	CERT
Response to PR Notice	PRN

Other Regulatory Submissions

Submission Type	Distribution Code
Total Release of Fog	FOG
Electronic Data Submission for EDSP	E-Sub PRD-EDSP
Unreasonable Adverse Effects Data Report	6(a)(2)
Emergency Exemption	EMEX
Experimental Use Permit	REGFEE
Genetically Modified and/or Nonindigenous Microbial Pesticide Pre-EUP Notifications	BIOTECH
Minor Use (IR-4) Petition	R4
Special Local Need Registration	SLN
Supplemental (Distributor) Registration	DIST
Notifications	NOTIF
Data Submitters List	DSL
Voluntary Cancellation	VOLCAN
Voluntary Use Deletion	USEDEL
Maintenance Fees	MFEE
Reconstruction of Jacket	RECON
Inert Ingredient Actions	INERT
Spray Drift Reduction Technology Program	SDRTP
Water Soluble Packaging amendments where mixing directions changes are due to an Agency initiated action	WSP

Administrative Actions

Submission Type	Distribution Code
Request for a Company Number	NEWCO

AR0000691

Submission Type	Distribution Code
Company Name, Address or Agent Change	COADR
Transfer of Companies, Products or Data	XFER

Data Call-In Responses (Product Specific)

Submission Type	Distribution Code
Response to a Data Call-In	DCI-RD-PMxx
Response to a Reregistration Eligibility Document	RED-RD-PMxx

> **Note**: (xx identifies the PM Team number)

Data Call-In Responses (Generic)

Submission Type	Distribution Code
Response to a Data Call-In	DCI-PRD-xxx
Response to a Reregistration Eligibility Document	RED-PRD-xxx
Response to EDSP Data Call-In	EDSP-PRD-xxx

> **Note**: (xxx identifies the regulatory case number or chemical name as specified in individual OPP instructions)

Where to Send Applications for Pesticide and Pesticide Device Producing Establishments

Applications for pesticide-producing establishments and reports for pesticide producing establishments should be sent to the following:

AR0000692

For Domestic Establishments:

Applications should be sent to the EPA Regional Office having jurisdiction over the state in which the company headquarters is located.

For Foreign Establishments:

Foreign companies should submit their application to:

Michelle Stevenson
U.S. Environmental Protection Agency
Agriculture Division (2225A)
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001
Telephone number: (202) 564-2280

Where to Send Notices of Arrival of Pesticides and Devices

19 CFR 12.112 (PDF) <https://www.govinfo.gov/content/pkg/cfr-2012-title19-vol1/pdf/cfr-2012-title19-vol1-sec12-112.pdf> (2 pp, 184.54 K) requires an importer desiring to import pesticides or devices into the United States to submit EPA Form 3540-1, Notice of Arrival of Pesticides and Devices, to the U.S. EPA prior to the arrival of shipment in the United States. The completed form should be sent to the appropriate Regional office where the import will be occurring. EPA Regional Offices and the states that they cover are listed in the instructions on the form. More information about importing pesticides <https://epa.gov/compliance/importing-and-exporting-pesticides-and-devices>.

Organizational Charts

Links to the organizational charts for the Office of Chemical Safety and Pollution Prevention (OCSPP), the Office of Pesticide Programs (OPP), the Office of Enforcement and Compliance Assurance (OECA), and EPA Regional Offices are presented below.

- OCSPP <https://epa.gov/aboutepa>
- OPP <https://epa.gov/pesticide-contacts>
- OECA <https://epa.gov/aboutepa/about-office-enforcement-and-compliance-assurance-oeca>
- EPA Regions <https://epa.gov/pesticide-contacts/pesticide-contacts-our-regional-offices>

Contacting EPA

The following Web pages list individuals to contact for:

- Applications, Fees and Registration Information <https://epa.gov/pesticide-contacts/contacting-epa-about-regulating-pesticides-issues>
- Registration Ombudsman <https://epa.gov/pesticide-contacts/contacting-epa-about-regulating-pesticides-issues>
- Conventional pesticide products <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-registration-division>
- Antimicrobial pesticide products <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division>
- Biopesticides and Pollution Prevention Division - Branch Chiefs <https://epa.gov/pesticide-contacts/contacts-office-pesticide-programs-biopesticides-and-pollution-prevention>
- Science Policy and Topics <https://epa.gov/pesticide-contacts/contacting-epa-about-pesticides-science-and-policy-issues>
- General Topics <https://epa.gov/pesticide-contacts>

Pesticide Registration Home <https://epa.gov/pesticide-registration>

About Pesticide Registration <https://epa.gov/pesticide-registration/about-pesticide-registration>

Electronic Submission of Applications <https://epa.gov/pesticide-registration/electronic-submissions-pesticide-applications>

Pesticide Registration Manual <https://epa.gov/pesticide-registration/pesticide-registration-manual>

Fees and Waivers <https://epa.gov/pesticide-registration/pesticide-registration-fees-and-fee-waivers>

Registration Information by Type of Pesticide <https://epa.gov/pesticide-registration/registration-information-type-pesticide>

— Antimicrobial Registration <https://epa.gov/pesticide-registration/antimicrobial-pesticide-registration>

— Biopesticide Registration <https://epa.gov/pesticide-registration/biopesticide-registration>

— Conventional Registration <https://epa.gov/pesticide-registration/conventional-pesticide-registration>

— Inert Ingredient Regulation <https://epa.gov/pesticide-registration/inert-ingredients-regulation>

Requirements and Guidance <https://epa.gov/pesticide-registration/registration-requirements-and-guidance>

— Data <https://epa.gov/pesticide-registration/data-requirements-pesticide-registration>

— Forms <https://epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

— Labeling <https://epa.gov/pesticide-registration/labeling-requirements>

Contact Us <https://epa.gov/pesticide-registration/forms/contact-us-about-pesticide-registration> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON SEPTEMBER 26, 2022


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

March 6, 2000

PESTICIDE REGISTRATION (PR) NOTICE 2000 - 1*

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS
AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Applicability of the Treated Articles Exemption to Antimicrobial Pesticides

This notice clarifies current EPA policy with respect to the scope of the "treated articles exemption" in 40 CFR 152.25(a). This exemption covers qualifying treated articles and substances bearing claims to protect the article or substance itself. EPA does not regard this exemption as including articles or substances bearing implied or explicit public health claims against human pathogens. This notice addresses the types of claims which are not permitted for antimicrobial pesticide products exempt from registration under this provision and gathers together in one place guidance the Agency has offered in recent years on labeling statements which it believes would or would not be covered under this provision. This notice also explains the requirement that the pesticide in a treated article be "registered for such use."

This notice provides guidance to producers and distributors of pesticide treated articles and substances, and to producers and distributors of pesticides used as preservatives to protect treated articles from microbial deterioration.

I. BACKGROUND

EPA regulations in 40 CFR 152.25(a) exempt certain treated articles and substances from regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) if specific conditions are met. The specific regulatory language is:

Section 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation

"(a) *Treated articles or substances.* An article or substance treated with, or containing, a pesticide to protect the treated article or substance itself (for example, paint treated with a pesticide to protect

* This version makes corrections to the February 3, 2000 PR Notice 2000-1. Corrections in bold/italics or editorial deletions were made on pages 3, 4, 7, and 9.

the paint coating, or wood products treated to protect the wood against insect or fungus infestation),
if the pesticide is registered for such use."

Known as the "Treated Articles Exemption," section 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing a pesticide, if:

(1) the incorporated pesticide is registered for use in or on the article or substance, and;
(2) the sole purpose of the treatment is to protect the article or substance itself.

The exemption gives two examples of treatments that are intended to protect only the treated article or substance itself. In the first case, paint is being protected from deterioration of the paint film or coating. In the second case, wood is being protected from fungus or insect infestations which may originate on the surface of the wood. Pesticides used in this manner are generally classified as preservatives. Other pesticides are incorporated into treated articles because of their ability to inhibit the growth of microorganisms which may cause odors or to inhibit the growth of mold and mildew. Because of this treatment, it is claimed that a fresher and more pleasing surface can be maintained.

To qualify for the treated articles exemption, both conditions stated above must be met. If both are not met, the article or substance does not qualify for the exemption and is subject to regulation under FIFRA.

In recent years, the marketplace has experienced a proliferation of products that are treated with pesticides and bear implied or explicit public health claims for protection against bacteria, fungi and viruses, as well as specific claims against pathogenic organisms which may cause food poisoning, infectious diseases or respiratory disorders. Examples of such articles include toothbrushes, denture cleansers, children's toys, kitchen accessories such as cutting boards, sponges, mops, shower curtains, cat litter, vacuum cleaner bags, pillows, mattresses and various types of finished consumer textiles. In many cases, these products have made public health claims that extend beyond the protection of the article itself, and thus, they do not qualify for the treated articles exemption.

II. TYPES OF ANTIMICROBIAL CLAIMS

A. Public Health Claims

Because consumers have long associated the following widely used claims and references to microorganisms harmful to humans with products providing public health protection, EPA considers an article or substance to make a public health claim if any of the following claims are made either explicitly or implicitly:

1. A claim for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include *Mycobacterium tuberculosis, Pseudomonas aeruginosa, E. coli, HIV,*

Streptococcus and *Staphylococcus aureus*.

2. A claim for the product as a sterilant, disinfectant, virucide or sanitizer, regardless of the site of use of the product, and regardless of whether specific microorganisms are identified.

3. A claim of "antibacterial," "bactericidal," or "germicidal" activity or references in any context to activity against germs or human pathogenic organisms implying public health related protection is made.

4. A claim for the product as a fungicide against fungi infections or fungi pathogenic to man, or the product does not clearly indicate it is intended for use against non-public health fungi.

5. A claim to control the spread of allergens through the inhibition or removal of microorganisms such as mold or mildew.

6. A non-specific claim that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.

7. An unqualified claim of "antimicrobial" activity. Refer to Unit IV.C.

B. Non-Public Health Claims

EPA considers a product to make a non-public health claim if any of the following applies:

1. A claim to inhibit the growth of mildew on the surface of a dried paint film or paint coating.

2. A claim to inhibit microorganisms which may cause spoilage or fouling of the treated article or substance.

3. A claim to inhibit offensive odors in the treated article or substance.

4. EPA considers terms such as "antimicrobial," "fungistatic," "mildew-resistant," and " preservative," as being acceptable for exempted treated articles or substances provided that they are properly, and very clearly, qualified as to their intended non-public health use. Refer to Unit IV.C. Use of these terms in product names or elsewhere in the labeling in bolder text than accompanying information may render such qualifications inadequate.

III. PAST EPA LABELING CLAIMS INTERPRETATIONS

A. Odor and Mildew-Resistant Properties May Be Claimed

Over the past twenty-five years the Agency has issued several interpretations concerning the

exemption from FIFRA regulations ***of*** certain types of antimicrobial treated article claims associated with mildew-resistant paint, films and coatings. In the same period, EPA has also issued other interpretations concerning certain types of odor-resistant antimicrobial treated article claims.

During this period there has been widespread dissemination and adoption by the antimicrobial pesticide product community of these EPA interpretations regarding mildew-resistant and odor-resistant claims under the "treated articles exemption." Furthermore, the Agency continues to treat these general types of claims as covered by the term "to protect the treated article or substance itself" because mitigation of these non-public health related organisms can contribute to the protection of the appearance and maintenance of the intended useful life of the treated article or substance. Because during this period, there has also been widespread misinterpretation of EPA's guidance, the Agency has developed a representative set of statements designed to clarify its position in this area. Consequently, if they otherwise qualify for the exemption, properly labeled treated articles and substances bearing claims such as those described under Unit IV.B. continue to be eligible for the treated articles exemption.

B. Product Names May Not Contain Public Health Claims

The Agency regards trademarked product names of treated articles or substances [or references to trademarked names of registered pesticides] as potential sources of public health claims that could render a product ineligible for the "treated articles exemption" just as could other direct or indirect public health claims on or in a product's packaging or in its labeling or advertising literature. The Agency has maintained this position in enforcement actions against pesticide-treated articles, such as pesticide-treated cutting boards and other items, which bore names suggesting health or other benefits beyond mere preservation of the treated article itself. In determining the eligibility of a treated article or substance for the exemption, the Agency will examine the product name, its context, labeling claims and other related elements on a case-by-case basis

IV. TREATED ARTICLE LABELING CLAIMS

Products treated with antimicrobial pesticides with claims such as those described in Section A below are likely to not be acceptable under the "treated articles exemption" because they imply or express protection that extends beyond the treated article or substance itself. Products treated with antimicrobial pesticides registered for such use and which only bear claims for protection of the article or substance itself such as those described in Section B below are likely to be acceptable and eligible for the "treated articles exemption", assuming all other conditions have been met. Section C below contains examples of appropriate qualifying and prominence statements which have been extracted from multiple enforcement proceedings dealing with claims that can be made for treated articles without obtaining registration.

A. Examples of Labeling Claims That the Agency is Likely to Consider Unacceptable Under the Exemption

The following examples are not intended to be an all-inclusive listing of unacceptable treated article labeling claims. If persons are not sure whether their antimicrobial pesticides are covered by the provisions of this section, the Agency encourages them to request a written opinion from the Antimicrobials Division at one of the addresses listed under Unit VII.

These examples represent claims or types of claims for a treated article that would lead to a requirement to register the article as a pesticide product.

o Antibacterial

o Bactericidal

o Germicidal

o Kills pathogenic bacteria.

o Effective against E. coli and Staphylococcus.

o Reduces the risk of food-borne illness from bacteria.

o Provides a germ-resistant surface.

o Provides a bacteria-resistant surface.

o Surface kills common gram positive and negative bacteria.

o Surface controls both gram positive and negative bacteria.

o Surface minimizes the growth of both gram positive and negative bacteria.

o Reduces risk of cross-contamination from bacteria.

o Controls allergy causing microorganisms.

o Improves indoor air quality through the reduction of microorganisms.

B. Examples of Labeling Claims the Agency is Likely to Consider Acceptable Under the Exemption

The following examples are not intended to be an all-inclusive listing of acceptable treated article labeling claims. If persons are not sure whether their antimicrobial pesticides are covered by the provisions of this section, the Agency encourages them to request a written opinion from the

Antimicrobials Division at one of the addresses listed under Unit VII.

1. Mold and Mildew Resistant Claims

o This article has been treated with a fungistatic agent to protect the product from fungal growth.

o Mildew Resistant - treated with a fungistatic agent to protect the paint itself from the growth of mildew.

o Mildew Resistant - This paint contains a preservative which inhibits the growth of mildew on the surface of this paint film.

o Mildew Resistant - Extends useful life of article by controlling deterioration caused by mildew.

o Algae Resistant - This article contains a preservative to prevent discoloration by algae.

o A fungistatic agent has been incorporated into the article to make it resistant to stain caused by mildew.

o Article treated to resist deterioration by mold fungus.

o Article treated to resist deterioration from mildew.

o The fungistatic agent in this article makes it especially useful for resisting deterioration caused by mildew.

o Dry coating of this paint mildew resistant.

o Dried paint film resists mold fungus.

o Dry enamel coating resists discoloration from mildew.

o Cured sealant is mildew resistant.

o Dried film resists stains by mold.

o A mold or mildew resisting component has been incorporated in this article to make its dry film mildew resistant.

o Specially formulated to resist mildew growth on the paint film.

o Gives mildew-resistant coating.

o The mildew resistance of this outside house paint film makes it especially useful in high humidity areas.

o Retards paint film spoilage.

o Resists film attack by mildew.

2. Odor Resistant Claims

o This product contains an antimicrobial agent to control odors.

o This product contains an antimicrobial agent to prevent microorganisms from degrading the product.

o Resists Odors - This product has been treated to resist bacterial odors.

o Inhibits the growth of bacterial odors.

o Resists microbial odor development.

o Retards the growth and action of bacterial odors.

o Guards against the growth of odors from microbial causes.

o Guards against degradation from microorganisms.

o Reduces odors from microorganisms.

o Odor-resistant.

o Acts to mitigate the development of odors.

C. Antimicrobial Qualifying and Prominence Considerations

EPA does not believe that claims such as "antimicrobial," "fungistatic," "mildew-resistant," and " preservative" or related terms are consistent with the intent of 40 CFR 152.25(a) if they are: (1) part of the name of the product; or (2) not properly qualified as to their intended non-public health use. Examples of ***permissible*** statements would include, but not be limited to: "Antimicrobial properties built in to protect the product" and "Provides mildew-resistant dried paint coating." All references to the pesticidal properties and the required qualifying statements should be located together, should be printed in type of the same size, style, and color, and should be given equal prominence. Moreover, such references should not be given any greater prominence than any other described product feature.

In addition, treated articles or substances intended for microbial odor control or article preservation in areas where food-borne or disease-causing organisms may be present have the potential to create the impression that the article provides protection against food-borne and disease-causing bacteria. This potential should be addressed through very careful narrowing and qualification of the non-public health claims. A complete assurance that there is no misleading impression could be achieved through use of language like: "This product does not protect users or others against food-borne (or disease-causing) bacteria. Always clean this product thoroughly after each use." or " This product does not protect users or others against bacteria, viruses, germs or other disease organisms. Always clean this product thoroughly after each use."

V. ADDITIONAL INFORMATION

A. Registration of Treated Articles Making Public Health Claims

Treated articles or substances with implied or explicit public health claims or which otherwise fail to qualify for exemption are pesticide products subject to all requirements of FIFRA. They may not be legally sold or distributed unless they are registered with EPA or unless such claims have been removed and the article otherwise qualifies for exemption. To obtain a registration, an applicant must submit acceptable data supporting all the proposed claims under which the product will be marketed and meet all other applicable registration requirements. Refer to 40 CFR Parts 152, 156, and 158.

The Agency currently has no established protocols for the development of data to support public health claims on treated articles for which registration is sought. Acceptable protocols for product testing reflecting actual use conditions need to be submitted and approved by EPA prior to the development of these data. As part of this review process, the Agency will require that these protocols be independently validated for accuracy and reproducibility. Antimicrobial treated articles requiring registration must meet the same efficacy performance standards that are required for corresponding antimicrobial public health products. For any questions regarding the need for registration or the registration requirements for specific treated articles or substances, contact the Antimicrobials Division at the address listed under Unit VII.

B. The Term "Registered for Such Use"

In order to qualify for the treated articles exemption, 40 CFR 152.25(a) specifies that an article or substance must be treated with, or contain, a pesticide to protect the treated article or substance itself. The terms "treated with, or containing, a pesticide" and "if the pesticide is registered for such use" in 40 CFR 152.25(a) refer to actual incorporation or adding of an antimicrobial pesticide specifically registered for that use. To qualify under the "treated articles exemption" (assuming the article or substance otherwise qualifies), it is not sufficient that the antimicrobial pesticidal substance in the treated article merely resemble or have activity like a registered pesticide. The antimicrobial pesticide in the treated article or substance must be present in the article or substance solely as the result of

incorporating an antimicrobial pesticide which is registered for treating the specific article or substance.

Because of the wide range of exposure scenarios associated with the use of treated articles such as cutting boards and conveyor belts used in the food processing industry, and the wide range of household consumer uses, the Agency has interpreted 40 CFR 152.25(a) to mean that the registration and the labeling of the antimicrobial pesticide intended for incorporation into the treated article or substance needs to include specific listings of the articles or substances that may be treated. Accordingly, in registration actions over the past several years, EPA has not permitted broad general use patterns, such as the preservation of hard surfaces, plastics, adhesives or coatings for the registered pesticide. Instead, it has required that specific listings such as toys, kitchen accessories and clothing articles be reflected in the product registration and labeling as a prerequisite for incorporation of the pesticide into an article or substance under 40 CFR 152.25(a).

VI. EFFECTIVE DATE AND PROCEDURES

In order to remain in compliance with FIFRA and avoid regulatory or enforcement consequences as described here and below, it is the Agency's position that producers, distributors, and any other person selling or distributing pesticide treated articles and substances not in compliance with the Agency's interpretation of 40 CFR 152.25(a), as clarified by this notice, need to bring their products, labeling and packaging, any collateral literature, advertisements or statements made or distributed in association with the marketing ***(sale or distribution)*** of the treated article or substance into full compliance with the regulation as clarified by this notice as soon as possible.

Because some of the elements of this interpretation may not have been well understood by the regulated community, the Agency expects that some companies may need up to a year in order to comply with those elements that have been clarified by this notice. Therefore, for the present, the Agency is following the approach set forth in the April 17, 1998 **Federal Register** (63 FR 19256). Although non-public health claims for microbial odor control and mold and mildew claims associated with deterioration, discoloration, and staining were not specifically mentioned in the April 17, 1998 **Federal Register**, such claims are also consistent with the enforcement approach set forth in that notice, as well as with this guidance, provided that they are properly, and very clearly, qualified as to their non-public health use. The Agency will begin to rely on the guidance provided in this Notice on February 11, 2001. Products in commerce after that date ***which make statements, etc. that do not reflect the clarification offered in this notice*** would risk being considered out of compliance with 40 CFR 152.25(a).

VII. ADDRESSES

By mail:
Antimicrobials Division (7510C)
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D. C. 20460-0001

By courier:
Antimicrobials Division (7510C)
U. S. Environmental Protection Agency
Room 300, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

VIII. FOR FURTHER INFORMATION CONTACT

If you have questions about the content of this notice, you should contact Debra Edwards at (703) 308-7891.

/signed/

Marcia E. Mulkey, Director
Office of Pesticide Programs

An official website of the United States government

Consumer Products Treated with Pesticides

On this page:

- Background
- Tips to control microorganisms
- How products treated with pesticides are regulated
- Enforcement
- For more information

Background

The presence of microorganisms (bacteria, fungi and viruses) in or on various items has become of increased concern to consumers. In response to these concerns, many products (e.g., cutting boards, kitchen sponges, cat litter, toothbrushes and juvenile toys) are being treated with antimicrobial pesticides. Antimicrobial pesticides are substances or mixtures of substances used to destroy or limit the growth of microorganisms, whether bacteria, viruses, or fungi -- many of which are harmful -- on inanimate objects and surfaces.

How Products Treated with Pesticides are Regulated

The term "treated articles" typically refers to items that are treated with an antimicrobial pesticide to protect the item itself. The pesticides are usually added to the products (e.g., plastic shower curtain) during manufacture; however, they may be added after manufacture but before use of the article (e.g., incorporation of a pesticide in paint).

Tips to Control Microorganisms

These are some common sense steps you can take to reduce the spread of microorganisms. For example:

- Wash hands frequently and thoroughly, especially if you think you have been in contact with harmful microorganisms.
- Wash surfaces that contact food (e.g., utensils, cutting boards, counter tops) with a detergent and warm water.
- Wash children's hands and toys regularly.

These treated products often claim to protect the public against harmful microorganisms. These fall into a regulatory category of implied or explicit public health pesticidal claims.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the registration of any substance intended to prevent, destroy, repel, or mitigate pests. However, the Code of Federal Regulations prescribes the conditions under which an exemption from registration is allowed for treated articles or substances. It allows an exemption for:

> An article or a substance treated with or containing a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insects or fungus infestation), if the pesticide is registered for such use.

EPA grants the treated articles exemption for a non-public-health use of a pesticide that is intended to protect only the treated article or substance itself. Consumers may distinguish such products by the absence of the EPA's pesticide registration number of the registered pesticide used for protecting the article itself. An EPA registration number would be found on the product label. It should be noted that the EPA registration number would also be absent from an illegal product that should be registered. Products that qualify for this exemption must display appropriate clarifying statements. For example:

- Claims for treated articles or substances are limited to statements like, "This product contains a preservative (e.g., fungicide or insecticide) built in or applied as a coating only to protect the product. An example of an acceptable label statement would be:
  - Antimicrobial properties are built in to inhibit the growth of bacteria that may affect this product. The antimicrobial properties do not protect users or others against bacteria, viruses, germs, or other disease organisms. Always clean and wash this product thoroughly before and after each use.
- Treated kitchen accessories or other food contact articles such as a cutting board, high chair or conveyor belt that may come in contact with food should carry an appropriately qualifying statement, such as:
  - This product does not protect users or others against food-borne bacteria. Always clean and wash this product thoroughly before and after each use.
- Treated products such as bed pans and potty seats that involve potential human contact with bodily fluids or excrement (e.g., blood, vomit, saliva, urine or feces) should carry an appropriate qualifying statement, such as:
  - This product does not protect users against bacteria, viruses or other disease organisms. Always clean and wash this product thoroughly before and after each use.
- In addition, it should be noted that:
  - The treated articles exemption is available only for the protection of the product and not for public health uses.
  - The preservative claim and qualifying statement on the product packaging (type, size, color) must be given no greater prominence than other described product features.

Articles or products that claim to be effective in controlling microorganisms such as E. coli, S. aureus, Salmonella sp. or Streptococcus sp. must be registered as a pesticide. These articles or products make a public health claim that goes beyond the preservation of the treated article itself. EPA requires the submission of chemical data in support of the public health labeling claims and patterns of use of the product.

If EPA determines that such a product is exempt from registration as a pesticide, the product may claim only that it contains a pesticidal preservative to protect the product itself. These pesticides are known as materials preservatives. In these cases, the pesticide is registered for the intended use, and the sole purpose of treatment is to protect the product itself. These pesticides are widely used in the manufacture of textiles, plastics, paper, adhesives and coatings.

Any pesticide-treated product that is not registered by EPA must not make public health claims, such as "fights germs, provides antibacterial protection, or controls fungus." EPA's policy is predicated on the fact that no scientific evidence exists that these products prevent the spread of germs and harmful microorganisms in humans.

Enforcement

FIFRA does not allow companies to make public health pesticidal claims for any product distributed or sold unless the product has been approved and registered by EPA or is covered by an exemption from registration. EPA is concerned about these claims because, in addition to being unlawful, they are also potentially harmful to the public (e.g., if people believe that a product has a self-sanitizing quality, they may become lax in their hygiene practices). Practicing standard hygiene practices has been proven to prevent the transmission of harmful microorganisms and, therefore, reduce the possibility of public health risk.

In response to the marketing of unregistered pesticide-treated products with illegal, unsubstantiated public health claims, EPA has acted quickly and decisively to prohibit sales of such products. It will continue to be the Agency's policy to take action against companies that make such illegal claims.

Report a suspected violation <https://echo.epa.gov/report-environmental-violations>.

For More Information

- View or obtain an electronic copy of the guidance document (PR 2000-1) <https://epa.gov/pesticide-registration/prn-2000-1-applicability-treated-articles-exemption-antimicrobial-pesticides>.
- Questions On Pesticides? National Pesticide Information Center (NPIC) <http://npic.orst.edu/> 1-800-858-7378

Contact Us <https://epa.gov/safepestcontrol/forms/contact-us-about-pesticides-and-consumers> to ask a question, provide feedback, or report a problem.

LAST UPDATED ON JUNE 6, 2023


UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Discover.

Accessibility Statement <https://epa.gov/accessibility/epa-accessibility-statement>

Budget & Performance <https://epa.gov/planandbudget>

Contracting <https://epa.gov/contracts>

EPA www Web Snapshot <https://epa.gov/utilities/wwwepagov-snapshots>

Grants <https://epa.gov/grants>

No FEAR Act Data <https://epa.gov/ocr/whistleblower-protections-epa-and-how-they-relate-non-disclosure-agreements-signed-epa>

Plain Writing <https://epa.gov/web-policies-and-procedures/plain-writing>

Privacy <https://epa.gov/privacy>

Privacy and Security Notice <https://epa.gov/privacy/privacy-and-security-notice>

Connect.

Data.gov <https://www.data.gov/>

Inspector General <https://epa.gov/office-inspector-general/about-epas-office-inspector-general>

Jobs <https://epa.gov/careers>

Newsroom <https://epa.gov/newsroom>

Open Government <https://epa.gov/data>

Regulations.gov <https://www.regulations.gov/>

Subscribe <https://epa.gov/newsroom/email-subscriptions-epa-news-releases>

USA.gov <https://www.usa.gov/>

White House <https://www.whitehouse.gov/>

Ask.

Contact EPA <https://epa.gov/home/forms/contact-epa>

EPA Disclaimers <https://epa.gov/web-policies-and-procedures/epa-disclaimers>

Hotlines <https://epa.gov/aboutepa/epa-hotlines>

FOIA Requests <https://epa.gov/foia>

Frequent Questions <https://epa.gov/home/frequent-questions-specific-epa-programstopics>

Follow.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 17 2022

THE ADMINISTRATOR

MEMORANDUM

SUBJECT: 1-142. Civil Judicial and Administrative Enforcement Actions, Inspections and Information Gathering Outside of Geographic Regional Boundaries

FROM: Michael S. Regan

TO: Assistant Administrator for Enforcement and Compliance Assurance
Regional Administrators
Regional Counsels
Regional Enforcement and Compliance Assurance Division Directors

1-142. Civil Judicial and Administrative Enforcement Actions, Inspections and Information Gathering Outside of Geographic Regional Boundaries (1200 TN 725)

A steadily increasing number of civil judicial and administrative enforcement actions address, or could address, noncompliance beyond a single regional boundary and involve multiple agency enforcement organizations. U.S. Environmental Protection Agency delegations of enforcement authority to regions, however, generally follow regional boundaries and organizational lines.[1]

I hereby delegate to the regional administrators the authority to conduct inspections, gather information and engage in civil judicial and administrative enforcement actions outside of the geographic boundaries of their regions on behalf of other regions, as detailed below. In addition, I delegate the authorities to issue a final order, ratify a consent agreement and serve as a presiding officer, as detailed below. These broader authorities may be exercised only if a multi-regional enforcement coordination agreement is in place between the affected regions and, unless waived, the Office of Enforcement and Compliance Assurance.

---

[1] Introduction to the 1200 Delegations Manual, paragraph 2.8 (Jan. 1, 2021), available at https://intranet.epa.gov/ohr/rmpolicy/ads/dm/intro.htm. There are, however, exceptions to the general rule. *Id.* at para. 3.3 ("The Administrator may choose, however, to delegate authority to one regional administrator to exercise on behalf of all regions due to the delegated region's expertise or to further efficiencies when an action involves more than one region."); *see, e.g.*, Delegation 2-107 (designating Region 7 as a Center of Excellence for biosolids enforcement); Delegations 7-177 and 12-44 (designating Region 5 as a Center of Excellence for ozone-depleting substances and asbestos hazards enforcement); and Delegation 12-45 (delegating all regional administrators the authority to enforce titles I, IV and VI of the Toxic Substances Control Act outside of the boundaries of their respective regions).

This delegation does not apply to matters that otherwise would be commenced at EPA headquarters. This delegation does not limit or rescind any authority granted under the delegations referenced in section 1 to any delegatee, including regional administrators or the assistant administrator for OECA, nor does it change any of the limitations in those delegations.[2] This delegation does add other limitations that apply to the cross-regional exercise of those authorities.

1. AUTHORITY.

a. To carry out the authorities delegated to the regional administrators in the following delegations for conducting inspections, information gathering, and administrative and civil judicial enforcement outside the geographic boundaries of the region, as set forth below:

i. Delegations 2-13, 2-14-A, 2-22, 2-51, 2-52-A, 2-52-B, and 2-89, pursuant to the Clean Water Act;

ii. Delegations 3-1-A, 3-1-B, and 3-1-C, pursuant to the Marine Protection, Research and Sanctuaries Act;

iii. Delegations 5-8, 5-9, 5-14, 5-15-A, 5-15-B, and 5-17-A, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act;

iv. Delegations 7-6-A, 7-6-B, 7-6-C, 7-8, 7-16, 7-17, 7-19 (except as relates to Section 211), 7-22-A, 7-33, 7-41-A, 7-41-B, 7-42, 7-43, 7-44, 7-45, 7-46, and 7-47, pursuant to the Clean Air Act;

v. Delegations 8-8, 8-9-A, 8-9-B, 8-9-C, 8-10-A, 8-20, 8-24, 8-25, 8-26, 8-27, 8-31, 8-32, 8-33, 8-37, 8-39, 8-49, and 8-57, pursuant to the Solid Waste Disposal Act;

vi. Delegations 9-7-A, 9-7-B, 9-12, 9-16-A, 9-28, 9-32, 9-33-A, 9-33-B, 9-34, 9-35, 9-47, and 9-62, pursuant to the Safe Drinking Water Act;

vii. Delegations 12-1, 12-2-A, 12-2-B, 12-2-C, 12-2-D, and 12-3-A, pursuant to the Toxic Substances Control Act;

viii. Delegations 14-6, 14-12, 14-31, and 14-32, pursuant to the Comprehensive Environmental Response, Compensation and Liability Act;

ix. Delegation 21-5, pursuant to the Act to Prevent Pollution from Ships;

x. Delegations 22-1, 22-3-A, 22-3-B, and 22-3-C, pursuant to the Emergency Planning and Community Right-to-Know Act; and

[2] In addition, nothing in this delegation affects the delegation of authority related to areas of Indian country that cross regional boundaries: Delegation 1-140.

xi. Delegations 37-2, 37-3, 37-4, 37-5, and 37-6, pursuant to the Mercury Containing and Rechargeable Battery Management Act.

b. To the extent not already covered by any delegation referenced above, to issue a final order following payment of a proposed penalty as provided under 40 C.F.R. § 22.18(a) or to ratify a consent agreement under 40 C.F.R. § 22.18(b).

c. To the extent not already covered by any delegation referenced above, to serve as a presiding officer in any proceeding under subpart I of 40 C.F.R. part 22 or until the respondent files an answer in any proceeding under of 40 C.F.R. part 22 to which subpart I does not apply, as provided in 40 C.F.R. § 22.4(b).

2. **TO WHOM DELEGATED**. Regional administrators, for matters occurring outside of the geographic boundaries of their respective regions.

3. **LIMITATIONS**.

a. The authorities in section 1 may not be exercised unless a written multiregional enforcement coordination agreement is entered into between the region(s) exercising the delegated authority, the region(s) on whose behalf the acting region is exercising the delegated authority and, unless waived, the Office of Enforcement and Compliance Assurance. Any region may elect to not participate in the multiregional action. Such agreements may be case-specific or may cover a set of investigations or cases. The initial multiregional enforcement coordination agreement for each matter or set of matters must be signed by managers no lower than the directors of Enforcement and Compliance Assurance divisions in Regions 1-10, or their designees, and by the division director(s) in OECA, or their designee(s). The multiregional enforcement coordination agreement also must be signed by the regional counsel, or designee, for each participating region if there is a regional counsel role in the underlying delegation(s).

b. In the event of inconsistencies between the multiregional enforcement coordination agreement and any delegation referenced in section 1.a, the delegation will govern.

c. In the event of inconsistencies between this delegation and any delegation referenced in section 1.a, the delegation listed in section 1.a will govern.

d. The CERCLA authorities in section 1.a.viii are limited to the enforcement of release reporting requirements pursuant to Section 103 of CERCLA.

4. **REDELEGATION AUTHORITY**.

a. The authorities in section 1.a may be redelegated to the same level otherwise allowed by the relevant delegations referenced in section 1.a.

b. Regional administrators may redelegate the authority in section 1.b to one or more regional judicial officers.

c. Regional administrators shall redelegate the authority in section 1.c to one or more regional judicial officers.

d. An official who redelegates an authority retains the right to exercise or withdraw the authority. Redelegated authority may be exercised by any official in the chain of command, including deputies, to the official to whom it has been specifically redelegated. This section 4.d shall not apply to the authority in section 1.c.

5. ADDITIONAL REFERENCES.

a. Sections 308, 309 and 311 of the CWA.

b. Sections 104B and 105 of the MPRSA.

c. Sections 8, 9, 14 and 16 of FIFRA.

d. Sections 113, 114, 205, 208, 213 and 307 of the CAA.

e. Sections 3007, 3008, 9005 and 9006 of the SWDA.

f. Sections 1414, 1423 and 1445 of the SDWA.

g. Sections 11 and 16 of TSCA.

h. Section 109 of CERCLA.

i. 33 U.S.C. §§ 1902 and 1907 of the APPS.

j. Section 325 of EPCRA.

k. Section 5 of the MCRBMA.

l. "Nationally Significant Issues List Updates," Rosemarie Kelley (Oct. 28, 2020) (or most recent version of the NSI memorandum).

m. "Procedures for Determining Level of Federal Facility Enforcement Office Involvement in Nationally Significant Federal Facility Enforcement and Compliance Issues," Karin Leff (December 21, 2021) (or most recent version of this memo).

THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JAN 18 2017

MEMORANDUM

SUBJECT: Delegation of Authority 5-12, Issuance of Stop Sale, Use or Removal Orders

FROM: Gina McCarthy

TO: Assistant Administrator
Office of Enforcement and Compliance Assurance

Regional Administrators

5-12. Issuance of Stop Sale, Use or Removal Orders (1200 TN 350 5-12)

1. **AUTHORITY.** To issue stop sale, use or removal orders as provided in the Federal Insecticide, Fungicide and Rodenticide Act, including Section 13(a), whenever there is reason to believe on the basis of inspection or tests that a pesticide or device is in violation of any provision of FIFRA or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions or when the registration of the pesticide has been cancelled by a final order or has been suspended.

2. **TO WHOM DELEGATED.** Regional administrators and the assistant administrator for the Office of Enforcement and Compliance Assurance.

3. **LIMITATIONS.**
   a. Regional administrators may exercise the above authority against persons in their region. Regional administrators may also exercise the above authority against persons in another region after consulting with that region.
   b. The regional administrator must obtain the advance concurrence of the regional counsel, or equivalent, on the legal sufficiency of the action before exercising this authority. The regional counsel, or equivalent, may waive concurrence in writing.
   c. The assistant administrator for OECA must notify any affected regional administrators before exercising any of the above authorities, however, a regional administrator may waive this notification requirement.

4. **REDELEGATION AUTHORITY.**

   a. This authority may be redelegated to the section chief level, or equivalent, and no further.
   b. An official who redelegates an authority retains the right to exercise or withdraw the authority. Redelegated authority may be exercised by any official in the chain of command to the official to whom it has been specifically redelegated.

This paper is printed with vegetable-oil-based inks and is 100-percent postconsumer recycled material, chlorine-free-processed and recyclable.

5. **ADDITIONAL REFERENCES.**

a. Chapter 5 delegation titled "Civil Judicial Enforcement Actions" and "Emergency Temporary Restraining Orders" for seizure and related authority under Sections 13(b)–(d).

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

5-12. Issuance of Stop Sale, Use or Removal Orders

1. **AUTHORITY.** To issue stop sale, use, or removal orders as provided in the Federal Insecticide, Fungicide and Rodenticide Act, including Section 13(a), whenever there is reason to believe on the basis of inspection or tests that a pesticide or device is in violation of any provision of FIFRA, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been cancelled by a final order or has been suspended.

2. **TO WHOM DELEGATED.** Director, Enforcement and Compliance Assurance Division.

3. **LIMITATIONS.**

   a. This authority may be exercised against persons in Region 8. This authority also may be exercised against persons in another region after the official with the delegated authority or designee consults with that region.

   b. Any person exercising this authority must obtain the advance concurrence of the regional counsel or designee on the legal sufficiency of the action before exercising this authority. The RC may waive concurrence in writing.

4. **REDELEGATION AUTHORITY.**

   a. This authority may be redelegated to the section chief level, or equivalent, and no further.

   b. An official who redelegates an authority retains the right to exercise or withdraw the authority. Redelegated authority may be exercised by any official in the chain of command down to the official to whom it has been specifically redelegated.

5. **ADDITIONAL REFERENCES.** Chapter 5 delegations entitled "Civil Judicial Enforcement Actions" and "Emergency Temporary Restraining Orders" for seizure and related authority under Sections 13(b)–(d).

D H Th

Debra H. Thomas
Acting Regional Administrator

APR 2 9 2019

Date

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

5-12. Issuance of Stop Sale, Use or Removal Orders

1. **AUTHORITY.** To issue stop sale, use, or removal orders as provided in the Federal Insecticide, Fungicide and Rodenticide Act, including Section 13(a), whenever there is reason to believe on the basis of inspection or tests that a pesticide or device is in violation of any provision of FIFRA, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been cancelled by a final order or has been suspended.

2. **TO WHOM DELEGATED.** Chief, Air Enforcement Branch.

3. **LIMITATIONS.**

   a. This authority may be exercised against persons in Region 8. This authority also may be exercised against persons in another region after the official with the delegated authority or designee consults with that region.

   b. Any person exercising this authority must obtain the advance concurrence of the regional counsel or designee on the legal sufficiency of the action before exercising this authority. The RC may waive concurrence in writing.

4. **REDELEGATION AUTHORITY.**

   a. This authority may be redelegated to the section chief level, or equivalent, and no further.

   b. An official who redelegates an authority retains the right to exercise or withdraw the authority. Redelegated authority may be exercised by any official in the chain of command down to the official to whom it has been specifically redelegated.

5. **ADDITIONAL REFERENCES.** Chapter 5 delegations entitled "Civil Judicial Enforcement Actions" and "Emergency Temporary Restraining Orders" for seizure and related authority under Sections 13(b)–(d).

Suzanne J. Bohan, Director
Enforcement and Compliance Assurance Division

9/5/19
Date

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

5-12. Issuance of Stop Sale, Use or Removal Orders

1. **AUTHORITY.** To issue stop sale, use, or removal orders as provided in the Federal Insecticide, Fungicide and Rodenticide Act, including Section 13(a), whenever there is reason to believe on the basis of inspection or tests that a pesticide or device is in violation of any provision of FIFRA, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been cancelled by a final order or has been suspended.

2. **TO WHOM DELEGATED.** Chief, Pesticides and Toxics Enforcement Section.

3. **LIMITATIONS.**

   a. This authority may be exercised against persons in Region 8. This authority also may be exercised against persons in another region after the official with the delegated authority or designee consults with that region.

   b. Any person exercising this authority must obtain the advance concurrence of the regional counsel or designee on the legal sufficiency of the action before exercising this authority. The RC may waive concurrence in writing.

4. **REDELEGATION AUTHORITY.**

   a. This authority may not be redelegated.

   b. An official who redelegates an authority retains the right to exercise or withdraw the authority. Redelegated authority may be exercised by any official in the chain of command down to the official to whom it has been specifically redelegated.

5. **ADDITIONAL REFERENCES.** Chapter 5 delegations entitled "Civil Judicial Enforcement Actions" and "Emergency Temporary Restraining Orders" for seizure and related authority under Sections 13(b)–(d).

Scott Patefield, Chief
Air Enforcement Branch

9/19/19
Date

From: Henderson, Dedre
To: Tokarz, Christine
Subject: RE: Annual Revenue -when you get a moment!
Date: Wednesday, February 8, 2023 11:35:39 AM

This is somewhat better.

Todd Emerson
todd@james-enterprise.com

James Enterprises, Inc.
Westlaw
Annual sales: $1,423,622- estimated (last update 7/30/2022)
Employees: 33

From: Tokarz, Christine <tokarz.christine@epa.gov>
Sent: Wednesday, February 8, 2023 8:18 AM
To: Henderson, Dedre <Henderson.Dedre@epa.gov>
Subject: RE: Annual Revenue -when you get a moment!

Dedre,

Since Berkey is a DBA, is it possible to see if James Enterprise has a different annual revenue?

The Berkey one seems low based on the evidence I collected at the inspection.

James Enterprise, Inc.
https://james-enterprise.com/

Thanks!

Chris

From: Henderson, Dedre <Henderson.Dedre@epa.gov>
Sent: Tuesday, February 7, 2023 11:05 AM
To: Tokarz, Christine <tokarz.christine@epa.gov>
Subject: RE: Annual Revenue -when you get a moment!

Chris- here is the sales information:

Berkey Filters, Inc.

Reference Solutions/Experian

Sales: $730,000 (updated September 2022)
Employees: 11

From: Tokarz, Christine <tokarz.christine@epa.gov>
Sent: Monday, February 6, 2023 5:46 PM
To: Henderson, Dedre <Henderson.Dedre@epa.gov>
Subject: Annual Revenue -when you get a moment!

Hi Dedre!

If you get a chance can you get annual revenue for these folks?

Berkey Filters, Inc. (James Enterprise, Inc.)
1976 Aspen Circle
Pueblo, CO 81006
800-350-4170
www.berkeyfilters.com

James Enterprise, Inc.
https://james-enterprise.com/

Todd Emerson- Founder & CEO of James Enterprises, Inc.
todd@berkeyfilters.com

Renee Emerson
renee@berkeyfilters.com

Thanks!
Chris

https://rceweb.estado.pr.gov/en/entity-information/?c=365440-1511

CORPORATION INFORMATION

Corporation Information

BERKEY INTERNATIONAL LLC

Details | Articles | Annual Filings | Certificates

General Information

Name	BERKEY INTERNATIONAL LLC
Register No.	365440
Status	ACTIVE
Class	Limited Liability Company
Type	For Profit
Jurisdiction	Domestic
Formation Date	19-Nov-2015 04:10 PM
Effective Date	19-Nov-2015 04:10 PM
Expiration Date	Does not expire

Main Office

Street Address	Royal Industrial Park, B-2, 869 Km 1.5, Barrio Palmas, CATANO, PR, 00962
Mailing Address	PO Box 2206, OROCOVIS, PR, 00720

Resident Agent

Name	Shepherd , James B (Individual)
Street Address	Royal Industrial Park, B-2, 869 Km 1.5, Barrio Palmas, CATANO, PR, 00962
Mailing Address	PO Box 2206, OROCOVIS, PR, 00720

Authorized Persons

Name	Street Address	Mailing Address
Velez Silva, Xenia	235 Federico Costa St., Suite 310, Parque Las Americas I, SAN JUAN, PR, 00918	PO Box 11917, San Juan, SAN JUAN, PR, 00922

Administrators

Name	Title	Address
Shepherd , James B.	President	Royal Industrial Park, B-2, 869 Km 1.5, Barrio Palmas, CATANO, PR, 00962 PO Box 2206, OROCOVIS, PR, 00720

Purpose

Todos los propósitos lícitos bajo la ley

← Return to Search Results

Actions

Pay 2022 Annual Due

Pay Prior Year(s) Annual Due

Order Certificate of Good Standing

Order Certificate of Existence

Amend Entity

Cancel Entity

Convert

Merge / Consolidate

Manage Access

Payment Plan

Government of Puerto Rico

Department of State
of Puerto Rico

Navigation

Entrepreneurs

Foreigners

Travelers

Examination Boards

Resources

Regulation No. 8688

Act No. 55-2020

Act No. 164-2009

Puerto Rico's Treasury Department

Contact

San José with San Francisco Street
San Juan, Puerto Rico

PO Box 9023271
San Juan, Puerto Rico 00902-3271

© 2021 - 2022 Department of State. Government of Puerto Rico

Terms of Use Privacy Policy

From: Henderson, Dedre
To: Tokarz, Christine
Subject: Berkey International, LLC
Date: Monday, April 10, 2023 2:35:33 PM

Hi Chris-

Berkey International, LLC was registered in Puerto Rico in 2015.

James B. Shepherd- President (current registered agent)
PO Box 2206
OROCOVIS, PR 00720
(719) 221-5351
js-tw@startmail.com

Pérez Riera, Jose R. – (Previous registered agent until January 22, 2021)
2000 Kennedy Ave., Suite 315
SAN JUAN, PR, 00920
(787) 777-1919
jpr@predco.net

Westlaw:
Modeled (last updated 4/30/2021)
Annual sales $79,288 (??)
Employees: 6

Xenia Vélez- Attorney (from 2015 registration, may still be his attorney)
xv@mcvpr.com
Phone: 787-250-2620
https://www.mcvpr.com/attorneys

Katherine Betancourt -Paralegal (from 2021 amended registration)
https://sanchezlrv.com/

Registration history:
https://prcorpfiling.estado.pr.gov/CorpInfo/CorporationFilings.aspx

NYT Wirecutter - negative review of Berkey Water Filters, 2022
https://www.nytimes.com/wirecutter/reviews/big-berkey-water-filter-system/

This is more information that I thought would be available.

Dedre

Dedre Henderson, Librarian
Arctic Slope Mission Services
U.S. EPA Region 8 Technical Library
1595 Wynkoop Street, 8MSD/IMB | Denver, CO 80202-1129
w. 303-312-6745 | henderson.dedre@epa.gov

Library hours: 8:00-4:00, M-TR

Tell us how we're doing - rate our customer service!
https://forms.office.com/g/NmQEzE1mj2

From: Tokarz, Christine <tokarz.christine@epa.gov>
Sent: Thursday, April 6, 2023 9:51 AM
To: Henderson, Dedre <Henderson.Dedre@epa.gov>
Subject: Whoops one more

Hi Again!

I am assisting Region 2 with a Stop Sale Order for a location in Puerto Rico. If you are interested in the reading one of the 5 SSUROS that Region 8 issued for the filter manufacturers in our Region see attached .

And now I am drafting the one for Region 2, at their request.

Since we send some of these documents and communications by email- I was wondering if you could get some background on this company, and most especially some contacts?

Thanks a million- talk about a wide variety of company investigations this week! Haha!

Berkey International
Royal Industrial Park, B-2
869 Km 1.5, Barrio Palmas
Catano, Puerto Rico 00962

Not sure if this site is helpful, but just in case: https://www.berkeywater.com/authorized-international-dealers/

Christine Tokarz
FIFRA Inspector
EPA, Region 8
tokarz.christine@epa.gov

O:303-312-6147
C:518-416-8965
Tips for FIFRA Imports: https://www.cbp.gov/document/publications/ace-tips-filing-epa-pesticides
File a Tip or Complaint to EPA: https://echo.epa.gov/report-environmental-violations
Confidential: This transmission may contain deliberative, attorney-client, attorney work product or otherwise privileged material. Do not release under FOIA without appropriate review. If you have received this message in error, please delete it from your machine and all storage media, whether electronic or hard copy.

Login | ACE Secure Data Portal | PGA Data Processing: Details | Berkey Water Systems – Berkey

support.berkeywater.com

ACE | Compliance Monito... | EPA@Work | EPA@... | EPA FedTalent | Enforcement and C... | Time Sheets

Berkey® WATER SYSTEMS

ABOUT PRODUCTS SUPPORT & SERVICE BLOG Find a Dealer Become a Dealer



The Gold Standard in Gravity-Fed Water Purification

Berkey® systems equipped with **Black Berkey® Elements** reduce greater than 99.999% of viruses and greater than 99.9999% of pathogenic bacteria, while also removing or dramatically reducing protozoa, trihalomethanes, inorganic minerals, heavy metals, pharmaceuticals, pesticides, VOCs, petroleum products, perfluorinated chemicals, rust, silt, sediment and even radiologicals.

4-27-22.xlsx

Show all

Type here to search

47°F

2:16 PM 4/27/2022

Login | ACE Secure Data Portal | PGA Data Processing: Details | Products – Berkey Water Systems

support.berkeywater.com/products/

ACE | Compliance Monito... | EPA@Work | EPA@... | EPA FedTalent | Enforcement and C... | Time Sheets

Berkey

ABOUT PRODUCTS SUPPORT & SERVICE BLOG Find a Dealer Become a Dealer

Explore Berkey® systems, elements and accessories below. Then learn important buying information to ensure a great experience.

Outdoor Systems



Sport Berkey® Bottle



Go Berkey® Kit



Travel Berkey® System



Berkey Light® System

Multi-Use Systems

4-27-22.xlsx

Show all

Type here to search

47°F

2:18 PM 4/27/2022

Login | ACE Secure Data Portal | PGA Data Processing: Details | Products – Berkey Water Systems

support.berkeywater.com/products/

ACE | Compliance Monito... | EPA@Work | EPA@... | EPA FedTalent | Enforcement and C... | Time Sheets

Multi-Use Systems

Not all systems available in CA and IA.



Big Berkey® System



Royal Berkey® System



Imperial Berkey® System



Crown Berkey™ System



Selecting your system

4-27-22.xlsx

Show all

Type here to search

47°F

2:18 PM 4/27/2022

Login | ACE Secure Data Portal | BI launch pad | Qlik Sense | FAQ Berkey® Store | Any
berkey-store.com/en/faq/faq-water-filter-black-berkey/faq-silver-black-berkey-water-filter.html
ACE | PGA Data Processing | EPA@Work | EPA@... | Region 8 | EPA@Wo... | SharePoint Sites | Other Important St... | Another scam recor...

eed Help?

ASK A QUESTION

Faq categories

Black Berkey® filter elements (29)

Do Black Berkey® water filters contain silver?

That's right! Silver is used as an anti-microbial so that each Black Berkey® element can self-sterilize. Analysis was performed by an independent laboratory to ensure that the silver used does not dissolve in the purified water and this is exactly the case. The analysis concludes, "All control samples, including stock samples, positive and negative analytical controls, and the negative control collected prior to plating gave appropriate results and were accepted. Results for the leaching control samples (effluent sample spiked with MS2 and R. terrigena and analyzed at two time points) were quite similar, suggesting that no active antimicrobial agents dissolved in the treated water."

You can check the results in this full report.

Type here to search
Suns...
2:26 PM 12/13/2022

AR0000735-AR0000738

Contains CBI

Berkey International, LLC v. EPA

Case No. 3:24-cv-01106-CVR

AR0000739-AR0000741

Contains CBI

Berkey International, LLC v. EPA

Case No. 3:24-cv-01106-CVR

AR0000742-AR0000745

Contains CBI

Berkey International, LLC v. EPA

Case No. 3:24-cv-01106-CVR

AR0000746-AR0000747

Contains CBI

Berkey International, LLC v. EPA

Case No. 3:24-cv-01106-CVR

AR0000748-AR0001007

Contains CBI

Berkey International, LLC v. EPA

Case No. 3:24-cv-01106-CVR